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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION
- - -

IN RE: NATIONAL : HON. DAN A. POLSTER
POLSTER
PRESCRIPTION OPIATE :
LITIGATION :
APPLIES TO ALL CASES : NO.
: 1:17-MD-2804

- HIGHLY CONFIDENTIAL -
SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
- - -

JANUARY 17, 2019
- - -

VOLUME II

Videotaped sworn continued
deposition of TRACEY L. NORTON, taken
pursuant to notice, was held at BEST
WESTERN LEHIGH VALLEY HOTEL & CONFERENCE
CENTER, 300 Gateway Drive, Bethlehem,
Pennsylvania, beginning at 8:38 a.m., on
the above date, before Margaret M.
Reihl, a Registered Professional
Reporter, Certified Shorthand Reporter,
Certified Realtime Reporter, and Notary
Public.

- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax

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1 THE VIDEOGRAPHER: We're now on
2 the record. My name is Phillip Todd,
3 I'm a videographer for Golkow Litigation
4 Services. Today's date is January 17,
5 2019. The time is 8:38 a.m.

6 This video deposition is being
7 held in Bethlehem, PA in the matter of
8 National Prescription Opiate Litigation
9 for the United States District Court,
10 Northern District of Ohio, Eastern
11 Division. The deponent is Tracey
12 Norton. Counsel will be noted on the
13 stenographic record.

14 The court reporter is Peg Reihl
15 and will now swear in the witness.

16 ... TRACEY L. NORTON, having been
17 duly sworn as a witness, was examined
18 and testified further as follows:

19 BY MS. VANNI:

20 Q. Good morning, Tracey.
21 A. Good morning.
22 Q. Can you please introduce yourself
23 to the jury.
24 A. Yes, my name is Tracey Norton.

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1 Q. We've seen some documents over
2 the course of the last couple of days where you
3 were referred to as Tracey Hernandez.
4 Is that a previous name you used
5 to use?
6 A. Yes, it is.
7 Q. What is your educational
8 background?
9 A. I have a Bachelor's in business
10 from Muhlenberg University and a Master's in
11 pharmaceutical policy from the University of
12 Florida.
13 Q. And when did you earn your
14 Master's?
15 A. In -- my Master's was 2010.
16 Q. How long did it take you to earn
17 your Master's?
18 A. Two years.
19 Q. And can you give us a sense of
20 what your Master's involves.
21 A. Yes. It covered all different
22 types of regulations that apply to the
23 pharmaceutical industry, so FDA regulations,
24 drug approval, DEA regulations, state

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<p style="text-align: right;">Page 557</p> <p>1 regulations, basically the gamut of regulations 2 that apply to the industry. 3 Q. And why did you get your 4 Master's? 5 A. It was an area that I wanted to 6 pursue and make sure that I had a thorough 7 understanding, even beyond DEA compliance. 8 Q. When did you first begin working 9 at Qualitest? 10 A. In August of 2011. 11 Q. And when did you leave Qualitest? 12 A. In December of 2014. 13 Q. So you were there about three 14 years and a couple of months? 15 A. Yes, three years and four months. 16 Q. What was Qualitest's customer 17 base? 18 A. Primarily wholesalers and chains. 19 Q. And when you say "chains," what 20 are you referring to? 21 A. Chain drug stores. 22 Q. When you joined Qualitest, what 23 was your position? 24 A. The director of DEA compliance.</p>	<p style="text-align: right;">Page 559</p> <p>1 And then I also had a SOMS team 2 of SOMS manager and two associates. 3 Q. So SOMS was handled separately? 4 A. Yes, separate from the 5 manufacturing and distribution. 6 Q. I want to talk to you about some 7 of the components of DEA compliance program at 8 Qualitest based on what you just told us that 9 you handled on a day-to-day basis. 10 A. Sure. 11 Q. I believe one thing you just 12 mentioned was quota, so I want to talk to you 13 first a little about quota, okay? 14 A. Mm-hmm, yes. 15 Q. Before I do that, I want to ask 16 you whether you recall being shown a 17 demonstrative that plaintiff's counsel put 18 together yesterday, it's Exhibit 4. I think you 19 have it in front of you. 20 A. Yes, I do. 21 Q. It's called "Par Total Pills 22 Shipped 2008 - 2015." 23 A. Yes. 24 Q. Do you remember that?</p>
<p style="text-align: right;">Page 558</p> <p>1 Q. And during your time at 2 Qualitest, did your position change? 3 A. No. 4 Q. As director of DEA compliance, 5 can you explain to us a little bit of what you 6 were responsible for on a day-to-day basis? 7 A. Absolutely. I was responsible 8 for -- excuse me -- quota, recordkeeping, such 9 as dealing with DEA 222 forms, import and export 10 documentation, also end of year reporting, ARCOS 11 reporting, SOMS and training for employees. 12 Q. Did anyone report to you? 13 A. Yes. Ultimately, I had eight 14 people that reported to me. When I first 15 started there was one. 16 Q. And just, generally speaking, 17 what were the functions of those people who 18 reported to you? 19 A. So I had a person for each -- 20 each manufacturing and distribution facility, 21 and they were responsible for the overall 22 compliance of that facility, all of the 23 activities that I mentioned, the day-to-day 24 records and things like that.</p>	<p style="text-align: right;">Page 560</p> <p>1 A. Yes, I do. 2 Q. Counsel represented to you 3 yesterday that the information in this 4 demonstrative was based on information that Endo 5 had pointed him to. 6 Do you recall that? 7 A. I do. 8 Q. Have you ever seen any of the 9 underlying data referenced in this 10 demonstrative? 11 A. No, I have not. 12 Q. Do you know what the data 13 represents? 14 A. No. 15 Q. Do you know if the data reflects 16 sales? 17 A. I'm not sure. 18 Q. You mentioned yesterday that it 19 could reflect more than sales. 20 Do you have a recollection of 21 that? 22 A. Yes, yes, it could actually also 23 reflect transfers, when DEA refers to a sale 24 that can also be a transfer or a movement of</p>

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<p style="text-align: right;">Page 561</p> <p>1 product from your facility to somewhere else. 2 MR. BUCHANAN: Move to strike, 3 called for speculation. The witness' 4 answer was speculation. 5 BY MS. VANNI: 6 Q. Are you familiar with quota -- 7 A. Yes. 8 Q. -- and how quota is handled? 9 A. Yes, I am. 10 Q. Do you know if this demonstrative 11 is accurate? 12 A. No, I do not. 13 Q. Counsel also referred to 14 Qualitest as pumping pills out. 15 Do you recall that? 16 A. I do. 17 Q. Can you describe for the jury 18 what quota is? 19 A. Yes. So quota is a requirement 20 by DEA, it's basically a permission to purchase 21 a certain -- in Qualitest's case, it was a 22 permission to purchase a certain quantity of raw 23 material for each controlled substance family. 24 DEA regulates that amount every year, there's a</p>	<p style="text-align: right;">Page 563</p> <p>1 different departments at Qualitest to find out 2 what the needs of the department were. So if 3 there were any research projects that were going 4 on, if there were any transfers or validations 5 that were going on. 6 So, for example, if product was 7 being made in one piece of equipment and needed 8 to be transferred to a different piece of 9 equipment, you would have to make three 10 validation batches, that was an FDA requirement, 11 so we would need to get quota for that as well. 12 We would also have information on 13 destructions and information on sales, and we 14 would be submitting all of that information to 15 DEA and also answering any follow-up questions 16 that they had on those quotas. 17 Q. How often would you have to apply 18 for quota? 19 A. You would apply in April of the 20 prior year for the current year. That was your 21 initial submission, and then throughout the 22 year, as things changed, you would submit 23 additional quota requests if sales increased. 24 You could also surrender quota if you weren't</p>
<p style="text-align: right;">Page 562</p> <p>1 new quota assigned, and it's based on several -- 2 several different things that DEA considers, 3 information that the company provides as well as 4 information that DEA obtains elsewhere. 5 Q. Like what? 6 A. It's based on sales data that the 7 company provides. It's also based on 8 destruction data of material that's on hand. 9 It's based on prescriptions written, DEA does 10 review the IMS data that talks about 11 prescriptions and, you know -- so they're 12 looking for the medical need for the product. 13 It's also -- they also confer 14 with FDA on it as well, and it could also be for 15 commercial distribution, but the quota is also 16 used for research activities as well, validation 17 activities of validating new processes and 18 things like that. 19 Q. As part of your responsibilities 20 as DEA compliance manager, did you manage quota? 21 A. Yes. 22 Q. And what would that require you 23 to do? 24 A. We would interact with a lot of</p>	<p style="text-align: right;">Page 564</p> <p>1 using it. 2 Q. Could it be carried over? 3 A. No, it could not. It was 4 basically for that one year, and anything that 5 was not used in the permission by December 31st 6 was forfeited. 7 Q. Approximately how much of your 8 time was spent managing quota? 9 A. Probably about 40%. 10 Q. And as part of your 11 responsibilities in managing quota, would you 12 communicate with the DEA? 13 A. Yes, on a regular basis, mostly 14 with DEA headquarters. 15 Q. Based on your experience and 16 knowledge of how quota works, could Qualitest 17 just be pumping pills out, as counsel suggested? 18 A. No. 19 MR. BUCHANAN: Objection to form. 20 BY MS. VANNI: 21 Q. Why is that? 22 A. DEA basically regulates how much 23 we can make, and, again, it's based on a number 24 of factors, one of which is medical need.</p>

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<p style="text-align: right;">Page 565</p> <p>1 Q. You also mentioned, I believe you 2 said recordkeeping or end of year recordkeeping 3 reporting. 4 Can you tell the jury what that 5 is? 6 A. Yes. So every transfer that we 7 have of a Schedule I or II drug, which is what 8 oxycodone or hydrocodone was, every movement 9 that we make of those drugs is visible to DEA. 10 There's a form called a DEA 222 form, which is a 11 three-part form issued by DEA. The purchaser 12 receives a copy, the supplier receives a copy, 13 and DEA gets a copy. So they're aware of every 14 movement and every customer purchase of Schedule 15 I or Schedule II drugs. So that's the 222s. 16 Then we also did ARCOS reporting, 17 which is a quarterly report, could also be 18 monthly, depending on how the company wants to 19 submit it, but it's a quarterly report that sums 20 up all sales, all purchases. And by "sales," I 21 mean movement as well as actual sales. All 22 purchases, all transfers that we would make 23 within the company or externally, all of that is 24 recorded and submitted to DEA on a regular</p>	<p style="text-align: right;">Page 567</p> <p>1 investigate and you'll have to explain if you 2 can't account for everything. 3 Q. If you're not able to reconcile 4 your numbers, what do you have to do? 5 MR. BUCHANAN: Objection to form, 6 calls for narrative. 7 THE WITNESS: You would have to 8 report it to DEA if you can't reconcile, 9 and there could be a violation. 10 BY MS. VANNI: 11 Q. You were asked some questions 12 yesterday about the SOMS program at Qualitest. 13 Do you recall that? 14 A. Yes. 15 Q. First of all, can you define what 16 SOMS is? 17 A. Suspicious order monitoring 18 system. 19 Q. And why is -- is a SOMS program 20 important, in your view? 21 A. It is, yes. 22 Q. And why? 23 A. Because we need to make sure that 24 we're shipping product to customers that are</p>
<p style="text-align: right;">Page 566</p> <p>1 basis. So, again, they have additional 2 information about your movements. 3 And then at the end of the year, 4 we also did an end of year report, and that was 5 a full accountability of everything on site 6 of -- a large part of that is your end of year 7 inventory, and you count everything on site, and 8 then you reconcile to the prior year's 9 inventory, and that gets submitted to DEA as 10 well. 11 MR. BUCHANAN: Move to strike the 12 narratives, and, frankly, they should 13 proceed in a question, answer not with 14 narratives. 15 BY MS. VANNI: 16 Q. And why is end of year reporting 17 important? 18 A. It's important because it's a 19 total reconciliation and it shows that you are 20 able to account for all of your product. There 21 is some loss that's allowed by DEA, because they 22 expect that you're going to have some 23 manufacturing loss due to the processes, but 24 there's an unspoken percentage that DEA will</p>	<p style="text-align: right;">Page 568</p> <p>1 legitimate and that have legitimate use of the 2 product. 3 Q. You were asked some questions 4 yesterday about a DEA meeting that Qualitest had 5 in March of 2013. 6 Do you recall those? 7 A. I do. 8 Q. And I believe that counsel made 9 some reference to Qualitest being called to or 10 summoned to the DEA in DC, and I think you 11 referred to it as a different kind of meeting. 12 Can you describe the meeting that 13 Qualitest had with DEA in March of 2013? 14 A. Yes. 15 MR. BUCHANAN: Objection, 16 misstates the record. 17 THE WITNESS: DEA had a 18 distributor initiative that was ongoing 19 for several years, and it was their 20 intent to meet with all distributors, 21 all distributor registrants and to share 22 information, and it was really a meeting 23 where they were talking to industry 24 about some possible things that they</p>

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<p style="text-align: right;">Page 569</p> <p>1 could look at to improve their SOMS 2 program, as well as getting information 3 from industry as to what tools might be 4 out there, what they were doing that 5 could also be of value. Really looking 6 to partner to -- to help make the SOMS 7 programs the best it could be. 8 MR. BUCHANAN: Objection, move to 9 strike, lack of foundation. 10 BY MS. VANNI: 11 Q. Did you personally attend the 12 meeting? 13 A. I did. 14 Q. Did you interact with DEA at the 15 meeting? 16 A. I did, yes. 17 Q. Counsel showed you a variety of 18 documents yesterday to establish that you knew 19 about certain factors that went into having an 20 effective SOMS program. 21 Before you met with the DEA in 22 March of 2013, do you remember that line of 23 questioning? 24 A. Yes, I do.</p>	<p style="text-align: right;">Page 571</p> <p>1 to strike, absence of foundation. 2 BY MS. VANNI: 3 Q. And when you started at 4 Qualitest, were there some areas of improvement 5 that you wanted to address with respect to the 6 SOMS program? 7 A. Yes, there were. 8 Q. Okay. And what were some of 9 those areas? 10 A. I had heard at DEA conferences 11 that there were things that DEA thought that 12 industry could do to improve SOMS programs, such 13 as a customer questionnaire, a customer on-site 14 visits, putting boots on the ground, to visit 15 your customers, SOPs, chargeback data. Those 16 were all things that had come up at DEA 17 conferences in the past and that DEA was 18 suggesting could be helpful. 19 Q. Were they required by regulation? 20 A. They were not. 21 MR. BUCHANAN: Objection to form, 22 foundation. 23 BY MS. VANNI: 24 Q. Are you familiar with the</p>
<p style="text-align: right;">Page 570</p> <p>1 Q. In fact, I believe counsel's 2 question was something to the effect of you knew 3 what was important before the DEA meeting in 4 2013, right? 5 MR. BUCHANAN: Objection to form. 6 THE WITNESS: Yes. 7 BY MS. VANNI: 8 Q. Do you recall that? 9 A. I do. 10 Q. In fact, that's true, right? 11 A. It is very true. 12 Q. Is there any dispute about that? 13 A. No, not at all. 14 Q. Do you have an understanding, as 15 you sit here today, why Qualitest hired you in 16 2011? 17 A. I do. 18 Q. What is that? 19 A. Qualitest hired me to come in and 20 make improvements to the DEA program that they 21 wanted to have, and that includes all of the 22 recordkeeping quotas, SOMS, make improvements 23 across the board. 24 MR. BUCHANAN: Objection. Move</p>	<p style="text-align: right;">Page 572</p> <p>1 regulation? 2 A. I am, yes. 3 Q. I want to show you what plaintiff 4 used yesterday, I believe it was Exhibit 17. I 5 think you have it in front of you. 6 If you could go to I believe it's 7 page 574.24. 8 A. Yes. 9 Q. Under "Potential Failure 10 Mode/Effect." 11 Do you see where I am? 12 A. I do. 13 Q. It says, "Our current Suspicious 14 Order Monitoring Program (SOMS) was built in 15 pieces and only applies to the retail side of 16 the business." 17 A. Yes. 18 Q. "DEA requires it to apply to all 19 customers. In addition, the current system has 20 had two issues in the past year that resulted in 21 controlled product being released that should 22 not have been. The system needs to be revamped, 23 all customers added, IMS data and chargeback 24 data incorporated and eventually a contracted</p>

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<p>1 customer assessment firm hired or an on-site 2 SOMS specific individual to perform these 3 assessments." 4 Do you know who wrote this? 5 A. I did. 6 Q. Yesterday counsel had suggested 7 to you that this document was written in 8 January 2013 because it was attached to an 9 e-mail from that date. 10 Do you recall that? 11 A. Yes, I do. 12 Q. When was this document written? 13 A. This document was a living 14 document that was written from -- started at the 15 time when -- at the time that I was hired and as 16 I reviewed different areas, I added to the 17 document, on an ongoing basis. 18 Q. And what was the purpose of you 19 doing that? 20 A. To document things that I wanted 21 to improve at the company and to basically make 22 sure that we addressed all of them. 23 Q. Your comments with respect to the 24 current suspicious order monitoring program that</p>	<p>1 A. Yes. 2 MR. BUCHANAN: Objection, 3 foundation. 4 THE WITNESS: Creating a SOMS 5 program is an extremely involved 6 process, especially if you want to do it 7 right, and our -- we had to evaluate the 8 electronic systems that were available 9 to us, our own internal system to see if 10 it was capable of handling and our IT 11 structure to see if they could build -- 12 we could build our own system in-house 13 versus outsource it. We had to hire 14 people to manage the program on a 15 regular basis. We had to write SOPs. 16 We had to educate internal people on 17 what the program was about and how to 18 use it. And we had to make sure that we 19 had the capability to visit customers. 20 We had to review chargeback data. There 21 were a lot of different things that went 22 into developing an enhancement of that 23 program. 24</p>
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<p>1 I just read, were they -- was that based on 2 observations that you made? 3 A. It was. 4 Q. Can you estimate for us when you 5 started looking at the SOMS program at 6 Qualitest? 7 A. Basically -- 8 MR. BUCHANAN: Calls for 9 speculation. 10 THE WITNESS: -- when I started. 11 BY MS. VANNI: 12 Q. And I think we've established 13 that you started in 2011. Do you remember the 14 month? 15 A. August of 2011, yes. 16 Q. Tracey, did you wait until the 17 DEA meeting in March 2013 to start looking at 18 the SOMS program? 19 A. Absolutely not. 20 Q. If you started looking at the 21 SOMS program around the time you were first 22 hired at Qualitest, can you explain to the jury 23 why all of the changes that you wanted to make 24 were not implemented before March 2013?</p>	<p>1 BY MS. VANNI: 2 Q. You mentioned needing to hire 3 people? 4 A. Yes. 5 Q. Were you involved in the hiring 6 process? 7 A. I was. 8 Q. Can you describe a little bit for 9 us why that would take time? 10 A. It took a long time because of 11 the facility being in Huntsville, for one. It 12 was not -- not really in the pharmaceutical 13 belt, so it was a little bit difficult to find 14 someone who had applicable experience and then, 15 also, we wanted to -- I wanted to make sure that 16 we found the right person. I think it's a very 17 important role. So it definitely took a long 18 time to get the right person in and to write the 19 job descriptions as well. 20 Q. With respect to the DEA meeting 21 that you were questioned about yesterday, you 22 made a comment or provided testimony that 23 counsel moved to strike that the SOMS -- that 24 the DEA did not find Qualitest SOMS program</p>



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<p style="text-align: right;">Page 577</p> <p>1 inadequate.</p> <p>2 Do you recall that?</p> <p>3 A. I do, yes.</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p>	<p style="text-align: right;">Page 579</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p>
<p style="text-align: right;">Page 578</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p>	<p style="text-align: right;">Page 580</p> <p>1 Q. Yesterday you were shown</p> <p>2 Plaintiffs' Exhibit Number 5. You should have</p> <p>3 it in front of you. I can direct your attention</p> <p>4 to the second page of that document on Qualitest</p> <p>5 letterhead dated October 18, 2013?</p> <p>6 A. Yes.</p> <p>7 Q. Turn the back page of it, 594.4,</p> <p>8 is that your signature?</p> <p>9 A. Yes, it is.</p> <p>10 Q. Did you send this letter?</p> <p>11 A. I did.</p> <p>12 Q. What is -- what was the purpose</p> <p>13 in you sending this letter?</p> <p>14 A. The purpose of the letter was to</p> <p>15 notify our customers that we were going to be</p> <p>16 asking for additional information from them in</p> <p>17 the form of a questionnaire, that we were</p> <p>18 concerned we would be looking at orders in</p> <p>19 different ways than we had in the past and --</p> <p>20 Q. Different how?</p> <p>21 A. Different through the new</p> <p>22 electronic system, so those -- the information</p> <p>23 that the new electronic system would give us</p> <p>24 would be additional information. We may be</p>

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<p style="text-align: right;">Page 581</p> <p>1 coming back to the customers to ask questions, 2 and so it was really just notifying them that, 3 you know, they might get calls from us that they 4 did have to fill out this questionnaire, 5 basically putting them on alert to this change. 6 Q. If the customers did not fill out 7 questionnaires, would you take any steps or 8 actions or would anybody in your department? 9 A. Yes, we would follow up with them 10 at first to give them an opportunity. If it 11 didn't -- hadn't been sent to the correct 12 person, we wanted to make sure that it 13 absolutely did get to the right person. If they 14 didn't fill it out after that, then we would 15 take action against them as far as not servicing 16 them. 17 Q. If I could direct your attention 18 to the third paragraph, it's the second sentence 19 begins, "Qualitest is enhancing its due 20 diligence efforts when fulfilling orders to 21 provide greater assurance that our products are 22 purchased by appropriate patients for prescribed 23 uses." 24 Did I read that correctly?</p>	<p style="text-align: right;">Page 583</p> <p>1 Q. I believe you mentioned customer 2 visits as well? 3 A. Yes. 4 Q. Were you able to implement 5 customer visits after the DEA meeting? 6 A. We were, yes. 7 Q. And why did you want to do that? 8 A. It was one of the suggestions 9 that DEA had had, and I had seen it being 10 suggested by DEA previously as well. 11  12 13 14 15 16 17 18 19 20 21 22 23 24</p>
<p style="text-align: right;">Page 582</p> <p>1 A. Yes, you did. 2 Q. What did you mean by that 3 statement? 4 A. We wanted to make sure that we 5 were doing everything we could, meeting the 6 regulation, which is what we were doing 7 previously, but we also wanted to make sure that 8 we were building in some of the things that I 9 knew had been suggestions and feedback from DEA 10 in the past to make sure that we were doing 11 whatever we could to prevent our product from 12 getting into illegitimate hands. 13 Q. And I think we established you're 14 familiar with the DEA regulations? 15 A. Yes. 16 Q. The things that you were able to 17 implement during your time at Qualitest with 18 respect to the SOMS program, were they required 19 under the regulation? 20 MR. BUCHANAN: Objection to the 21 form, foundation. 22 THE WITNESS: No, they were not 23 required. 24 BY MS. VANNI:</p>	<p style="text-align: right;">Page 584</p> <p>1  2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24</p>

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<p style="text-align: right;">Page 585</p> <p>1 BY MS. VANNI:</p> <p>2 Q. And what time frame are we</p> <p>3 talking about here with respect to your</p> <p>4 description of the SOMS program, as you just</p> <p>5 provided it?</p> <p>6 A. As far as when did the customer</p> <p>7 visits start?</p> <p>8 Q. No, in terms of the questions</p> <p>9 that I was just asking you generally in terms of</p> <p>10 the SOMS program, how it operated, what time</p> <p>11 frame are you referring to?</p> <p>12 A. So the time frame of an order</p> <p>13 pending versus the investigation and all the</p> <p>14 happenings, so it --</p> <p>15 Q. My question was a little bit</p> <p>16 different.</p> <p>17 What years are we talking about</p> <p>18 that the SOMS program operated like this?</p> <p>19 A. Basically 2013, 2014.</p> <p>20 Q. You also when you were describing</p> <p>21 your overall DEA compliance responsibilities at</p> <p>22 Qualitest, you had mentioned training?</p> <p>23 A. Yes.</p> <p>24 Q. What do you mean by "training"?</p>	<p style="text-align: right;">Page 587</p> <p>1 on an ongoing basis across the employee.</p> <p>2 Q. Would you personally provide the</p> <p>3 training, or would people on your team do it?</p> <p>4 A. At first I was the main one</p> <p>5 providing the training. Certain specific</p> <p>6 training others gave, so, for example, our SOM</p> <p>7 manager gave specific SOMS training.</p> <p>8 Q. What kind of -- what's your</p> <p>9 understanding of what training Mr. Brantley</p> <p>10 would provide?</p> <p>11 A. Basically, why we needed the SOMS</p> <p>12 program.</p> <p>13 MR. BUCHANAN: Objection to form,</p> <p>14 foundation.</p> <p>15 THE WITNESS: What types of</p> <p>16 things we would look for and why it was</p> <p>17 important, things that we would</p> <p>18 document.</p> <p>19 BY MS. VANNI:</p> <p>20 Q. Prior to someone on your team</p> <p>21 giving training to someone in the company, would</p> <p>22 you have a discussion with them?</p> <p>23 A. We were discussing things with</p> <p>24 employees all the time, so it was really an</p>
<p style="text-align: right;">Page 586</p> <p>1 A. We did a lot of training for</p> <p>2 employees, a lot of different types of training.</p> <p>3 So the main one was the general</p> <p>4 overview, which covered I called it soup to nuts</p> <p>5 on the DEA regulations, all of the</p> <p>6 recordkeeping, the requirements, storage</p> <p>7 requirements, the general overview of quota, the</p> <p>8 need for the suspicious order monitoring. It</p> <p>9 covered everything.</p> <p>10 MR. BUCHANAN: Objection to form</p> <p>11 as to time again. I'm sorry it's</p> <p>12 belated, but if you want to correct it</p> <p>13 to clarify, I just wanted to give you</p> <p>14 notice.</p> <p>15 BY MS. VANNI:</p> <p>16 Q. When would you have implemented</p> <p>17 training?</p> <p>18 A. Basically when I started.</p> <p>19 Q. So we're talking like the 2011</p> <p>20 time frame?</p> <p>21 A. Correct.</p> <p>22 Q. And would the training be</p> <p>23 provided at different points in time?</p> <p>24 A. It would, yes. It was provided</p>	<p style="text-align: right;">Page 588</p> <p>1 ongoing education process, so we would train and</p> <p>2 talk to all employees, all levels.</p> <p>3 Q. Finally, you were asked some</p> <p>4 questions yesterday about some industry groups</p> <p>5 that you belong to, specifically the</p> <p>6 anti-diversion working group and the New Jersey</p> <p>7 Pharmaceutical Industry Group.</p> <p>8 Do you remember that?</p> <p>9 A. I do, yes.</p> <p>10 Q. Can you describe for the jury</p> <p>11 what the anti-diversion working group is?</p> <p>12 A. Yes, the anti-diversion working</p> <p>13 group was put together -- it consisted of</p> <p>14 manufacturers and distributors, it was a group</p> <p>15 that met maybe four times total. It --</p> <p>16 Q. What was the purpose of the</p> <p>17 group?</p> <p>18 A. The purpose of the group was to</p> <p>19 collaborate, to see if there was a way that we</p> <p>20 could impact abuse and diversion in a positive</p> <p>21 way, to help to prevent it, and we came up with</p> <p>22 the red flags video.</p> <p>23 Q. What is the red flags video?</p> <p>24 A. It's a video that's directed to</p>

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<p style="text-align: right;">Page 589</p> <p>1 pharmacies and pharmacists, and it basically</p> <p>2 talks about things that they should look for in</p> <p>3 patients or individuals that are seeking to</p> <p>4 divert the product.</p> <p>5 Q. What is the -- what was the</p> <p>6 purpose of that?</p> <p>7 A. The purpose was to make sure that</p> <p>8 pharmacists were aware of things to look for to</p> <p>9 help to prevent diversion. We were concerned</p> <p>10 about it and wanted to try to do whatever we</p> <p>11 could.</p> <p>12 Q. Do you know if the DEA was aware</p> <p>13 of this group?</p> <p>14 A. The DEA was aware of the group.</p> <p>15 DEA was actually -- I believe they were sent --</p> <p>16 also sent a copy of the video.</p> <p>17 MR. BUCHANAN: Objection move to</p> <p>18 strike, foundation.</p> <p>19 BY MS. VANNI:</p> <p>20 Q. You also were asked about your</p> <p>21 time at -- involved in the New Jersey</p> <p>22 Pharmaceutical Industry Group?</p> <p>23 A. Yes.</p> <p>24 Q. Do you recall that?</p>	<p style="text-align: right;">Page 591</p> <p>1 shared, but there is some detail shared.</p> <p>2 Q. And why did you decide to join</p> <p>3 these groups?</p> <p>4 A. The group actually started, the</p> <p>5 New Jersey working group actually started</p> <p>6 through a request from the local DEA, and DEA</p> <p>7 was looking to have a good working relationship</p> <p>8 with industry and to make sure that we,</p> <p>9 together, could do, you know, everything that we</p> <p>10 could from a prevention of abuse and diversion.</p> <p>11 MS. VANNI: At this point I don't</p> <p>12 have any further questions for you. I</p> <p>13 might have some follow-up after.</p> <p>14 THE WITNESS: Okay.</p> <p>15 MS. VANNI: Thank you. Pass the</p> <p>16 witness.</p> <p>17 MR. BUCHANAN: You can go off the</p> <p>18 record. Thank you.</p> <p>19 THE VIDEOGRAPHER: The time is</p> <p>20 now 9:13. We are off the record.</p> <p>21 (Brief recess.)</p> <p>22 THE VIDEOGRAPHER: 9:15, back on</p> <p>23 the record.</p> <p>24 BY MS. KOSKI:</p>
<p style="text-align: right;">Page 590</p> <p>1 A. Mm-hmm.</p> <p>2 Q. What is that?</p> <p>3 A. It's a working group of peers,</p> <p>4 others in the companies that handled DEA</p> <p>5 compliance, and the group gets together maybe</p> <p>6 once or twice a year, and the purpose is to</p> <p>7 share learnings of DEA regulations and to get</p> <p>8 industry to do benchmarking.</p> <p>9 Q. What is benchmarking?</p> <p>10 A. Basically to see what other</p> <p>11 companies are doing in some areas so --</p> <p>12 Q. Why is that important?</p> <p>13 A. It's important because it helps</p> <p>14 to -- helps to keep you abreast of what's new</p> <p>15 and what's developing. It also helps to know</p> <p>16 what's going on in other companies, because</p> <p>17 sometimes you might want to implement something</p> <p>18 internally and you're asked, you know, by others</p> <p>19 in your company, well, what are other companies</p> <p>20 doing? So to have that background and that</p> <p>21 knowledge, to a certain extent, obviously, there</p> <p>22 are, you know, pretty big confidentiality issues</p> <p>23 when you're dealing with people who are our</p> <p>24 competitors, so there's not a lot of detail</p>	<p style="text-align: right;">Page 592</p> <p>1 Q. Good morning, I introduced myself</p> <p>2 earlier on the record, but my name is Katie</p> <p>3 Koski, and I represent Anda, Inc.</p> <p>4 Over the course of your</p> <p>5 deposition you've been asked a lot of questions</p> <p>6 or we've heard a lot of answers about a couple</p> <p>7 of different concepts that I want to discuss</p> <p>8 with you this morning, concepts such as ordering</p> <p>9 limits or thresholds.</p> <p>10 Are you familiar with that</p> <p>11 concept?</p> <p>12 A. Yes.</p> <p>13 Q. And customer dispensing data or</p> <p>14 dispensed data.</p> <p>15 Do you recall talking about that?</p> <p>16 A. I do.</p> <p>17 Q. And we've heard reference to</p> <p>18 customer questionnaires, do you recall that?</p> <p>19 A. Yes.</p> <p>20 Q. And there have been references to</p> <p>21 electronic order monitoring or electronic order</p> <p>22 systems?</p> <p>23 A. Yes.</p> <p>24 Q. And I'd like to ask some</p>

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<p style="text-align: right;">Page 593</p> <p>1 questions about those concepts. 2 So you've worked in DEA 3 compliance for about 25 years; is that right? 4 A. Yes. 5 Q. And you understand when I refer 6 to DEA compliance that I mean working with a 7 company's obligations under the Federal 8 Controlled Substances Act, right? 9 A. I do. 10 Q. And you're familiar with that 11 statute? 12 A. Yes, I am. 13 Q. So if I referred to 21 USC 14 Section 801, you understand what that is; is 15 that right? 16 A. I understand the 21 USC, yes. 17 Q. Okay. And is it fair to say 18 throughout the course of your career, you had 19 occasion to review the statute? 20 A. I have. 21 Q. Okay. And you're familiar with 22 Section 823 of the Act, right? 23 A. I'm not sure exactly what 823 is 24 but...</p>	<p style="text-align: right;">Page 595</p> <p>1 MS. KOSKI: We'll agree to 2 disagree on that. 3 MR. BUCHANAN: That's fine. 4 BY MS. KOSKI: 5 Q. Ms. Norton, you're familiar with 6 the statute? 7 A. Yes. 8 Q. Having taken a look at it just 9 now, Exhibit 31, does that refresh your 10 recollection as to the statute? 11 A. Yes, I just wasn't sure offhand 12 what 823 was. 13 Q. And yesterday during the course 14 of your examination, you referred on several 15 occasions to statutes of regulations that govern 16 DEA compliance, the role that you served? 17 A. Yes. 18 Q. Okay. And if you refer to 19 Section 823, you see that that governs the 20 registration of pharmaceutical manufacturers and 21 distributors, right? 22 A. Yes, it does. 23 Q. And we talked at length yesterday 24 that you worked primarily for pharmaceutical</p>
<p style="text-align: right;">Page 594</p> <p>1 (Document marked for 2 identification as Par-Norton Deposition 3 Exhibit No. 31.) 4 BY MS. KOSKI: 5 Q. Okay. I'm going to hand you what 6 we've then marked as Exhibit 31. 7 MR. BUCHANAN: You said 31? 8 MS. KOSKI: Yes. 9 BY MS. KOSKI: 10 Q. And you recognize the document 11 that I handed you as Section 823 of the 12 Controlled Substances Act? 13 A. Yes, I do. 14 MR. BUCHANAN: Counsel, I just 15 wanted to note a preliminary objection. 16 I trust this is going to be fact 17 testimony. It doesn't sound like it to 18 me at this point, but I just wanted to 19 give you notice that this does not seem 20 to be related to the witness' experience 21 or at least my examination of the 22 witness, so I don't feel constrained by 23 whatever time you use if I need more 24 time.</p>	<p style="text-align: right;">Page 596</p> <p>1 manufacturers and then later in your career for 2 a distributor; is that right? 3 A. Yes, that's correct. 4 Q. Okay. And for both manufacturers 5 and distributors, Section 823 provides that the 6 Attorney General shall register an applicant to 7 manufacture or distribute controlled substances 8 if he determines such registration is consistent 9 with the public interest. 10 Do you see that? 11 A. Yes, I do. 12 Q. And Section 823 in front of you 13 also provides that "In determining the public 14 interest, the following factors shall be 15 considered," and then it lists several, which 16 includes maintenance of effective controls 17 against diversion of particular controlled 18 substances into other than legitimate medical, 19 scientific and industrial channels. 20 You see that, right? 21 A. Yes, I do. 22 Q. In fact, that's the only section 23 of the Controlled Substances Act that addresses 24 maintenance of effective controls against</p>

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<p style="text-align: right;">Page 597</p> <p>1 diversion, right?</p> <p>2 MR. BUCHANAN: Objection to the</p> <p>3 form, leading, and, frankly, you should</p> <p>4 do this with experts. This is also</p> <p>5 beyond yesterday. This is not fact</p> <p>6 testimony, counsel. Put it in a legal</p> <p>7 brief, get an expert, do something, but</p> <p>8 this is not appropriate redirect</p> <p>9 examination.</p> <p>10 MS. KOSKI: You may object as to</p> <p>11 form, if you want a standing objection</p> <p>12 other than your speech that you just</p> <p>13 gave, you can have it.</p> <p>14 MR. BUCHANAN: No, I think you</p> <p>15 should know the basis of the objection.</p> <p>16 This is beyond -- this is expert.</p> <p>17 MS. KOSKI: I don't need -- I</p> <p>18 don't need to know the basis of the</p> <p>19 objection. You can object as to form.</p> <p>20 BY MS. KOSKI:</p> <p>21 Q. And I'll repeat my question.</p> <p>22 This is the only section of the</p> <p>23 Controlled Substances Act that addresses</p> <p>24 maintenance of effective controls against</p>	<p style="text-align: right;">Page 599</p> <p>1 redirect.</p> <p>2 BY MS. KOSKI:</p> <p>3 Q. The Act doesn't mention --</p> <p>4 doesn't include the phrase suspicious order,</p> <p>5 right?</p> <p>6 MR. BUCHANAN: That is leading.</p> <p>7 THE WITNESS: The CFR</p> <p>8 mentions suspicious order.</p> <p>9 BY MS. KOSKI:</p> <p>10 Q. I'm talking about the statute in</p> <p>11 front of you, the Controlled Substances Act.</p> <p>12 MR. BUCHANAN: That's leading.</p> <p>13 THE WITNESS: It does not say it</p> <p>14 here, no.</p> <p>15 BY MS. KOSKI:</p> <p>16 Q. And you know that there is no</p> <p>17 reference in the Controlled Substances Act to a</p> <p>18 "suspicious order monitoring system," correct?</p> <p>19 MR. BUCHANAN: Objection to the</p> <p>20 leading, counsel.</p> <p>21 THE WITNESS: Not to a system.</p> <p>22 BY MS. KOSKI:</p> <p>23 Q. Okay. And there's no language in</p> <p>24 the section of the Controlled Substances Act</p>
<p style="text-align: right;">Page 598</p> <p>1 diversion, right?</p> <p>2 MR. BUCHANAN: It's leading.</p> <p>3 THE WITNESS: I think overall the</p> <p>4 regulations as a whole address in</p> <p>5 different ways those controls. It does</p> <p>6 reference that specific wording here.</p> <p>7 BY MS. KOSKI:</p> <p>8 Q. Okay. And in the Controlled --</p> <p>9 the Federal Controlled Substances Act, the</p> <p>10 statute, there's no mention of suspicious order;</p> <p>11 is that fair?</p> <p>12 MR. BUCHANAN: Objection to form</p> <p>13 and the leading, counsel. It's a new</p> <p>14 area. It should be direct examination.</p> <p>15 MS. KOSKI: I'm sorry. You can</p> <p>16 object as to form, and you can preserve</p> <p>17 your record as to form.</p> <p>18 MR. BUCHANAN: You're leading a</p> <p>19 witness on expert territory, counsel.</p> <p>20 It's highly improper.</p> <p>21 MS. KOSKI: It's a form</p> <p>22 objection. You can object as to form.</p> <p>23 MR. BUCHANAN: I'll just tell</p> <p>24 you, counsel, it's not appropriate</p>	<p style="text-align: right;">Page 600</p> <p>1 that you have in front of you that says to "know</p> <p>2 your customer," right?</p> <p>3 MR. BUCHANAN: Objection to the</p> <p>4 leading, counsel.</p> <p>5 THE WITNESS: No, there is not.</p> <p>6 BY MS. KOSKI:</p> <p>7 Q. And there's no section in the</p> <p>8 Controlled Substances Act in front of you that</p> <p>9 refers to dispense data or dispensing data,</p> <p>10 right?</p> <p>11 A. There is not.</p> <p>12 MR. BUCHANAN: Objection to the</p> <p>13 leading, counsel.</p> <p>14 BY MS. KOSKI:</p> <p>15 Q. And there's no mention of</p> <p>16 customer questionnaire in the Act either, right?</p> <p>17 A. There is not.</p> <p>18 MR. BUCHANAN: Objection to the</p> <p>19 leading.</p> <p>20 You just have to give me a moment</p> <p>21 to get my objections in. Apparently,</p> <p>22 there are going to be quite a few.</p> <p>23 THE WITNESS: I'm sorry.</p> <p>24 MR. BUCHANAN: Thank you.</p>

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<p style="text-align: right;">Page 601</p> <p>1 BY MS. KOSKI:</p> <p>2 Q. And the Act does not refer to</p> <p>3 internet pharmacies, right?</p> <p>4 MR. BUCHANAN: Objection to the</p> <p>5 leading.</p> <p>6 THE WITNESS: It does not.</p> <p>7 BY MS. KOSKI:</p> <p>8 Q. And there's no provision of the</p> <p>9 Act that states that distributors may not fill</p> <p>10 orders that are identified by them as</p> <p>11 potentially "suspicious orders"?</p> <p>12 MR. BUCHANAN: Objection to the</p> <p>13 leading, counsel.</p> <p>14 BY MS. KOSKI:</p> <p>15 Q. There's nothing in the Act in</p> <p>16 front of you that says that?</p> <p>17 MR. BUCHANAN: Objection to the</p> <p>18 leading. Those words, is that what</p> <p>19 you're saying?</p> <p>20 MS. KOSKI: Yes.</p> <p>21 MR. BUCHANAN: Leading.</p> <p>22 BY MS. KOSKI:</p> <p>23 Q. You can answer.</p> <p>24 A. The CFR --</p>	<p style="text-align: right;">Page 603</p> <p>1 MR. BUCHANAN: Did you serve a</p> <p>2 notice on this?</p> <p>3 MS. KOSKI: You can object as to</p> <p>4 form.</p> <p>5 MR. BUCHANAN: No, no, no, no.</p> <p>6 I'm objecting because you don't have the</p> <p>7 right to do this.</p> <p>8 If you want to do this with this</p> <p>9 witness, you need to serve a notice;</p> <p>10 otherwise, you're limited to the</p> <p>11 examination that I conducted.</p> <p>12 MS. KOSKI: And this is</p> <p>13 clearly visible --</p> <p>14 MR. BUCHANAN: This is not.</p> <p>15 MS. KOSKI: Well, we can --</p> <p>16 MR. BUCHANAN: You're using her</p> <p>17 as an expert.</p> <p>18 MS. KOSKI: This is within the</p> <p>19 scope.</p> <p>20 MR. BUCHANAN: Tender her as a</p> <p>21 26(a)(1) expert if you want to.</p> <p>22 MS. KOSKI: I'm sorry, I'm not</p> <p>23 using her as an expert.</p> <p>24 MR. BUCHANAN: Then we'll take</p>
<p style="text-align: right;">Page 602</p> <p>1 Q. Referring to the Controlled</p> <p>2 Substances Act in front of you. We'll talk</p> <p>3 about the CFR after that.</p> <p>4 A. No.</p> <p>5 Q. Okay. And the Act doesn't have</p> <p>6 any provision that requires distributors to</p> <p>7 create an ordering system that allows a customer</p> <p>8 to submit suspicious orders so that the</p> <p>9 distributor can then report those orders to the</p> <p>10 DEA, right? That's not in the language of the</p> <p>11 statute?</p> <p>12 MR. BUCHANAN: I'll object to the</p> <p>13 leading.</p> <p>14 THE WITNESS: No.</p> <p>15 MR. BUCHANAN: I'm also going to</p> <p>16 object to the examination, counsel.</p> <p>17 Did you serve a separate notice</p> <p>18 for this examination? This goes well</p> <p>19 beyond the direct examination.</p> <p>20 MS. KOSKI: It doesn't.</p> <p>21 MR. BUCHANAN: It does. Did you</p> <p>22 serve a separate notice?</p> <p>23 MS. KOSKI: If references all of</p> <p>24 the concepts that you discussed.</p>	<p style="text-align: right;">Page 604</p> <p>1 the full examination.</p> <p>2 MS. KOSKI: I'm using -- this is</p> <p>3 within the scope of your examination</p> <p>4 yesterday.</p> <p>5 MR. BUCHANAN: It's absolutely</p> <p>6 not. Does everybody here consent to</p> <p>7 this? Because if you do, it's going</p> <p>8 well beyond the time. We're going to</p> <p>9 kick open the door and we're going to go</p> <p>10 all morning.</p> <p>11 MS. KOSKI: I object to that.</p> <p>12 It's within the scope.</p> <p>13 MR. BUCHANAN: That's all right,</p> <p>14 we'll sit here.</p> <p>15 BY MS. KOSKI:</p> <p>16 Q. And you've heard reference</p> <p>17 throughout your deposition -- I think you</p> <p>18 actually referred to the term registrants,</p> <p>19 right?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And registrants are -- the</p> <p>22 term registrant is because of Section 823 that</p> <p>23 talks about the registration, right?</p> <p>24 MR. BUCHANAN: Objection to</p>

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<p style="text-align: right;">Page 605</p> <p>1 foundation and the leading.</p> <p>2 THE WITNESS: The registration.</p> <p>3 BY MS. KOSKI:</p> <p>4 Q. Okay. And when you referred to</p> <p>5 the term yesterday throughout your deposition as</p> <p>6 registrant, that was someone who was registered</p> <p>7 to either manufacture or distribute controlled</p> <p>8 substances pursuant to the Controlled Substances</p> <p>9 Act; is that correct?</p> <p>10 MR. BUCHANAN: Objection to form,</p> <p>11 leading.</p> <p>12 THE WITNESS: There are other</p> <p>13 types of registration as well.</p> <p>14 BY MS. KOSKI:</p> <p>15 Q. And you referred during your</p> <p>16 testimony yesterday to the DEA regulations that</p> <p>17 relate to the distribution and manufacture of</p> <p>18 controlled substances, right?</p> <p>19 A. Yes.</p> <p>20 Q. And I believe you referred to</p> <p>21 that -- the CFR, I think you referenced that, is</p> <p>22 that the Code of Federal Regulations?</p> <p>23 A. Yes, it is.</p> <p>24 Q. And is that what you were</p>	<p style="text-align: right;">Page 607</p> <p>1 THE WITNESS: Yes.</p> <p>2 BY MS. KOSKI:</p> <p>3 Q. And they don't make any mention</p> <p>4 of dispensing data?</p> <p>5 MR. BUCHANAN: Objection to form,</p> <p>6 leading.</p> <p>7 THE WITNESS: They do not.</p> <p>8 BY MS. KOSKI:</p> <p>9 Q. And they don't refer to customer</p> <p>10 questionnaires in the regulations, right?</p> <p>11 MR. BUCHANAN: Objection to form,</p> <p>12 leading.</p> <p>13 THE WITNESS: They do not.</p> <p>14 BY MS. KOSKI:</p> <p>15 Q. And one of the other things that</p> <p>16 you mentioned yesterday throughout your</p> <p>17 testimony is guidance from DEA.</p> <p>18 Do you recall that testimony?</p> <p>19 A. I do.</p> <p>20 Q. Okay. And as someone with your</p> <p>21 background in DEA compliance, you're familiar</p> <p>22 with the concept of guidance from the agency</p> <p>23 that regulates your business, right?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 606</p> <p>1 referring to when you said the DEA regulations</p> <p>2 that you used in your work as a compliance</p> <p>3 director?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And I believe you said the</p> <p>6 regulations are -- that's what you worked with</p> <p>7 more than the statute itself; is that right?</p> <p>8 MR. BUCHANAN: Objection to form</p> <p>9 and the leading.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. KOSKI:</p> <p>12 Q. Is that a fair summary of your</p> <p>13 testimony yesterday that the regulations are</p> <p>14 something you used as part of your roles and</p> <p>15 responsibilities as a director of compliance?</p> <p>16 MR. BUCHANAN: Objection,</p> <p>17 overbroad.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MS. KOSKI:</p> <p>20 Q. And you know that those</p> <p>21 regulations don't refer to "know your customer,"</p> <p>22 right?</p> <p>23 MR. BUCHANAN: Objection to form</p> <p>24 and the leading.</p>	<p style="text-align: right;">Page 608</p> <p>1 Q. Okay. And guidance sort of</p> <p>2 generally refers to the way the DEA as an agency</p> <p>3 itself or as individual employees of the DEA</p> <p>4 communicate with you as an industry participant;</p> <p>5 is that a fair summary?</p> <p>6 MR. BUCHANAN: Objection to form.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MS. KOSKI:</p> <p>9 Q. And as you talked about yesterday</p> <p>10 and I think earlier this morning as well, it may</p> <p>11 come in the form of a presentation given by</p> <p>12 representatives of the agency, right?</p> <p>13 MR. BUCHANAN: Objection to form.</p> <p>14 THE WITNESS: Yes, that's</p> <p>15 correct.</p> <p>16 BY MS. KOSKI:</p> <p>17 Q. Okay. And you've attended those</p> <p>18 types of presentations by DEA representatives?</p> <p>19 A. I have.</p> <p>20 Q. Okay. Could DEA guidance also</p> <p>21 come in the form of conversations between</p> <p>22 representatives of the industry and members of</p> <p>23 DEA?</p> <p>24 MR. BUCHANAN: Objection,</p>

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<p style="text-align: right;">Page 609</p> <p>1 foundation.</p> <p>2 THE WITNESS: Yes, it could.</p> <p>3 BY MS. KOSKI:</p> <p>4 Q. In your experience, has that</p> <p>5 actually happened?</p> <p>6 A. Yes, it has.</p> <p>7 Q. And you talked a lot about that</p> <p>8 yesterday in the context of your many years in</p> <p>9 the industry; is that fair?</p> <p>10 MR. BUCHANAN: Objection,</p> <p>11 overbroad.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MS. KOSKI:</p> <p>14 Q. Mr. Buchanan asked you about</p> <p>15 conversations you had with DEA agents?</p> <p>16 A. Yes.</p> <p>17 Q. And it may come in the form of</p> <p>18 written statements sent to one or more industry</p> <p>19 participant as well, guidance from the DEA that</p> <p>20 is?</p> <p>21 MR. BUCHANAN: Objection, form.</p> <p>22 THE WITNESS: Yes.</p> <p>23 BY MS. KOSKI:</p> <p>24 Q. And there's a -- is there a</p>	<p style="text-align: right;">Page 611</p> <p>1 continuing objection as to the scope of</p> <p>2 this examination.</p> <p>3 BY MS. KOSKI:</p> <p>4 Q. And by law enforcement, DEA acts</p> <p>5 as a sort of a police; is that fair?</p> <p>6 MR. BUCHANAN: Objection to form</p> <p>7 and the leading.</p> <p>8 THE WITNESS: Yes, there are</p> <p>9 agents.</p> <p>10 BY MS. KOSKI:</p> <p>11 Q. Okay. And they might investigate</p> <p>12 criminal activity, for example?</p> <p>13 A. Yes.</p> <p>14 Q. And they may refer cases to the</p> <p>15 Department of Justice for prosecution if they</p> <p>16 have reason to believe there's criminal activity</p> <p>17 happening within the industry.</p> <p>18 Are you familiar with that?</p> <p>19 A. Yes.</p> <p>20 Q. And now based on your testimony</p> <p>21 yesterday, your experience, is it fair to say,</p> <p>22 was more on the DEA's administrative or civil</p> <p>23 side of their responsibilities; is that fair?</p> <p>24 A. The meetings with DEA?</p>
<p style="text-align: right;">Page 610</p> <p>1 difference, in your mind, between the Controlled</p> <p>2 Substances Act that we marked as Exhibit 31 and</p> <p>3 the guidance in the form of conversations or</p> <p>4 presentations from DEA agents?</p> <p>5 MR. BUCHANAN: Objection to form.</p> <p>6 THE WITNESS: Yes, there is.</p> <p>7 BY MS. KOSKI:</p> <p>8 Q. Now, yesterday during the course</p> <p>9 of your testimony, you heard reference to things</p> <p>10 like notice of violation or I believe there was</p> <p>11 a reference to being summoned to the DEA and</p> <p>12 things like that.</p> <p>13 Do you recall that testimony?</p> <p>14 A. I do.</p> <p>15 Q. Okay. So I'd like to talk to you</p> <p>16 a little bit about your understanding of how DEA</p> <p>17 interacts with members of the industry.</p> <p>18 And so, for example, on one side</p> <p>19 of the house, DEA has some sort of, for lack of</p> <p>20 a better word, law enforcement responsibilities.</p> <p>21 Are you familiar with take?</p> <p>22 MR. BUCHANAN: Objection to form.</p> <p>23 THE WITNESS: Yes, I am.</p> <p>24 MR. BUCHANAN: I'll renew my</p>	<p style="text-align: right;">Page 612</p> <p>1 Q. Right.</p> <p>2 A. Yeah.</p> <p>3 Q. Those weren't criminal in nature</p> <p>4 that you're aware of?</p> <p>5 MR. BUCHANAN: Objection to form.</p> <p>6 THE WITNESS: No, they were not.</p> <p>7 BY MS. KOSKI:</p> <p>8 Q. Okay. And over the course of</p> <p>9 your testimony yesterday, I believe we saw some</p> <p>10 documents in reference to some meetings that</p> <p>11 would have been on behalf of DEA as the agency.</p> <p>12 Do you recall that?</p> <p>13 A. I'm sorry?</p> <p>14 Q. For example, we saw a letter</p> <p>15 issued a dear registrant letter I believe that</p> <p>16 you testified about yesterday.</p> <p>17 Do you recall that testimony?</p> <p>18 A. I do.</p> <p>19 Q. Okay. And is it your</p> <p>20 understanding that was a communication sent on</p> <p>21 behalf of the agency itself?</p> <p>22 A. Yes.</p> <p>23 Q. But you've also -- you also</p> <p>24 testified yesterday, in your experience, and</p>

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<p style="text-align: right;">Page 613</p> <p>1 correct me if I'm wrong with this, that you've</p> <p>2 engaged at a more sort of one-on-one level with</p> <p>3 representatives of the agency in the course of</p> <p>4 your business, right?</p> <p>5 MR. BUCHANAN: Objection to the</p> <p>6 leading.</p> <p>7 THE WITNESS: Yes.</p> <p>8 BY MS. KOSKI:</p> <p>9 Q. And on the administrative power</p> <p>10 side, which you testified being more familiar</p> <p>11 with, you're aware that DEA can take different</p> <p>12 actions against industry participants; is that</p> <p>13 right?</p> <p>14 MR. BUCHANAN: Objection to the</p> <p>15 form.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MS. KOSKI:</p> <p>18 Q. And you reference in some of your</p> <p>19 documents you referred to violations, I think</p> <p>20 you talked earlier about fines, possible</p> <p>21 administrative fines, right?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And as part of that,</p> <p>24 you're familiar that DEA can get a search</p>	<p style="text-align: right;">Page 615</p> <p>1 language from the DEA?</p> <p>2 MR. BUCHANAN: Same objection.</p> <p>3 THE WITNESS: Vaguely, yes.</p> <p>4 BY MS. KOSKI:</p> <p>5 Q. All right. So with all this sort</p> <p>6 of in mind, I'd like to refer you to Exhibit 2,</p> <p>7 which I believe you have in front of you and</p> <p>8 which counsel marked yesterday. And just for</p> <p>9 purposes of folks in the room, Exhibit 2 was an</p> <p>10 e-mail cover with a copy of Ms. Hernandez, then</p> <p>11 Hernandez, sorry, resume and then also a summary</p> <p>12 of suspicious order monitoring experience.</p> <p>13 Do you recall this testimony</p> <p>14 about this document?</p> <p>15 A. I do.</p> <p>16 Q. Okay. And as I understand it,</p> <p>17 you prepared Exhibit 2, I believe you testified</p> <p>18 yesterday, in connection with applying for a</p> <p>19 job; is that right?</p> <p>20 A. Yes.</p> <p>21 Q. Okay. And the date at least on</p> <p>22 the cover e-mail is October 2014.</p> <p>23 Do you see that?</p> <p>24 A. Yes.</p>
<p style="text-align: right;">Page 614</p> <p>1 warrant; is that right?</p> <p>2 A. Yes.</p> <p>3 Q. And they can compel a company to</p> <p>4 send individuals to appear before DEA and to</p> <p>5 testify under oath.</p> <p>6 Are you familiar with that?</p> <p>7 A. Yes.</p> <p>8 Q. And they can institute a formal</p> <p>9 proceeding like an enforcement action, right?</p> <p>10 Are you familiar with that?</p> <p>11 MR. BUCHANAN: Objection to form.</p> <p>12 This is so beyond the scope and so the</p> <p>13 subject for somebody who you're going to</p> <p>14 designate as an expert. You shouldn't</p> <p>15 be doing this in fact testimony,</p> <p>16 counsel.</p> <p>17 BY MS. KOSKI:</p> <p>18 Q. You're familiar with the roles</p> <p>19 and responsibilities of DEA over the course of</p> <p>20 your 25 years in the industry, right?</p> <p>21 A. Yes.</p> <p>22 Q. And there's also something called</p> <p>23 an order to show cause.</p> <p>24 Are you familiar with that</p>	<p style="text-align: right;">Page 616</p> <p>1 Q. Is that around or about the time</p> <p>2 that you prepared the summary of suspicious</p> <p>3 order monitoring?</p> <p>4 A. Yes, it is.</p> <p>5 Q. Okay. And so when you prepared</p> <p>6 this, this was about -- sorry, strike that.</p> <p>7 And on the second page of the</p> <p>8 document, you see there's a reference to Watson.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And that's Watson Laboratories,</p> <p>12 Inc.; is that right?</p> <p>13 A. Yes.</p> <p>14 Q. And you were employed by Watson</p> <p>15 Laboratories, Inc., right?</p> <p>16 A. I was.</p> <p>17 Q. Okay. And that's reflected in</p> <p>18 Exhibit 1, your resume, if you need to look at</p> <p>19 it.</p> <p>20 A. Yes.</p> <p>21 Q. And I believe on your resume it</p> <p>22 indicates you worked at Watson from 2002 to</p> <p>23 2009; is that right?</p> <p>24 A. Yes.</p>

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<p style="text-align: right;">Page 617</p> <p>1 Q. And so this document, Exhibit 2, 2 was prepared five years after you left Watson 3 Laboratories; is that right? 4 A. Yes, that's correct. 5 Q. And I think you testified 6 yesterday that you draft -- in the course of 7 drafting this document, you were trying to make 8 yourself look good to a potential employer; is 9 that fair? 10 MR. BUCHANAN: Objection to form. 11 THE WITNESS: That was what was 12 requested of me. 13 BY MS. KOSKI: 14 Q. And that's what you said 15 yesterday, right? 16 MR. BUCHANAN: Objection to form. 17 THE WITNESS: Yes. 18 BY MS. KOSKI: 19 Q. All right. And I want to just 20 look at some of the -- and I'm focused again on 21 the Watson section and some of the things that 22 you wrote. 23 And you wrote that while you were 24 employed by Watson, you did not support Anda</p>	<p style="text-align: right;">Page 619</p> <p>1 Q. Okay. And do you recall that the 2 meeting was in the summer of 2007? Does that 3 sound about right? 4 A. I don't recall when the meeting 5 was. 6 Q. Fair to say that it was sometime 7 during your employment at Watson? 8 A. Yes. 9 Q. And you wrote here that "Anda was 10 summoned to DEA." 11 Do you see that, and you spent 12 some time on that with counsel yesterday? 13 A. Yes. 14 Q. Okay. And we just went through 15 some of the ways in which the DEA exercises its 16 criminal and administrative powers, right? Do 17 you recall that; we just went through that? 18 A. I do. 19 Q. And you're familiar with that 20 from your experience, right? 21 A. Yes. 22 Q. And you'll agree with me that DEA 23 didn't issue any kind of a subpoena or some 24 legal process to bring Anda in to appear, right?</p>
<p style="text-align: right;">Page 618</p> <p>1 from a DEA perspective. 2 Do you see that? 3 A. Yes, that's correct. 4 Q. And that's an accurate statement, 5 right? 6 A. It is. 7 Q. Okay. You never worked for Anda, 8 Inc., right? 9 A. I did not. 10 Q. And you didn't work day to day in 11 Anda's compliance department, right? 12 A. I did not. 13 Q. And you weren't responsible for 14 oversight or for the actions of Anda's 15 compliance department, right? 16 A. I was not. 17 Q. I believe you testified yesterday 18 that -- and as I think you reference here, Anda 19 had its own compliance department when it was 20 acquired by Watson, right? 21 A. Yes. 22 Q. And in Exhibit 2 you describe a 23 meeting between Anda and DEA, right? 24 A. Yes.</p>	<p style="text-align: right;">Page 620</p> <p>1 MR. BUCHANAN: Leading. 2 THE WITNESS: They did not. 3 MR. BUCHANAN: Objection to form. 4 BY MS. KOSKI: 5 Q. Did DEA issue a warrant to Anda, 6 search warrant? 7 A. They did not. 8 Q. Okay. And you'll agree, won't 9 you, that DEA didn't issue any kind of formal 10 process like we talked about as it relates to 11 Anda, right? 12 MR. BUCHANAN: Objection, form, 13 leading. 14 THE WITNESS: No, they did not. 15 BY MS. KOSKI: 16 Q. And, of course, I'm focused on 17 the time period that you were at Watson and this 18 time period where you were dealing with this 19 meeting with Anda. 20 A. Understood. 21 Q. Okay. And so to the extent here 22 in your job application papers where you refer 23 to summoned, you didn't mean to say that DEA 24 issued a summons to Anda, right?</p>

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<p style="text-align: right;">Page 621</p> <p>1 A. I did not, no.</p> <p>2 Q. And as we said, Exhibit 2, that</p> <p>3 was in 2014, right?</p> <p>4 A. Yes.</p> <p>5 Q. So I want to refer you now --</p> <p>6 MR. BUCHANAN: I'm sorry,</p> <p>7 counsel, just so the record is clear,</p> <p>8 your last question was 2014, you're just</p> <p>9 referring to the date that this was</p> <p>10 prepared.</p> <p>11 BY MS. KOSKI:</p> <p>12 Q. I'm sorry, yes. The year of</p> <p>13 Exhibit 2 was 2014?</p> <p>14 A. Yes.</p> <p>15 Q. All right. And I'd like to</p> <p>16 focus, if we could, on the time period of the</p> <p>17 actual meeting that you referenced in Exhibit 2</p> <p>18 and talked a little bit about yesterday.</p> <p>19 Now, you recall that the -- you</p> <p>20 said that you weren't summoned in the formal</p> <p>21 sense, but that you -- do you recall that you</p> <p>22 received a phone call, you, Ms. Hernandez, at</p> <p>23 Watson as it related to this Anda issue with</p> <p>24 DEA?</p>	<p style="text-align: right;">Page 623</p> <p>1 A. Yes.</p> <p>2 Q. And is it fair to say he's the</p> <p>3 person with whom you were communicating about</p> <p>4 this issue?</p> <p>5 A. Yes.</p> <p>6 Q. Do you see there's a reference it</p> <p>7 says, "Mr. Mapes also offered to meet with us to</p> <p>8 discuss the issue and internet pharmacies in</p> <p>9 general in more detail."</p> <p>10 Do you see the reference to that?</p> <p>11 A. Yes, I do.</p> <p>12 Q. And does this refresh your</p> <p>13 recollection about the circumstances under which</p> <p>14 Anda was meeting with DEA in 2007?</p> <p>15 A. Yes.</p> <p>16 Q. So, in other words, in your</p> <p>17 Exhibit -- in Exhibit 2 where you referenced</p> <p>18 Anda being summoned in, that was written in</p> <p>19 2014, right?</p> <p>20 A. Yes.</p> <p>21 Q. But at the time of your</p> <p>22 conversations in 2007 with Mr. Mapes, you make a</p> <p>23 reference here that you were -- that Mr. Mapes</p> <p>24 offered to meet with Anda, right?</p>
<p style="text-align: right;">Page 622</p> <p>1 A. Yes, I did.</p> <p>2 Q. Sorry about that. My piles</p> <p>3 are -- here you go.</p> <p>4 (Document marked for</p> <p>5 identification as Par-Norton Deposition</p> <p>6 Exhibit No. 32.)</p> <p>7 BY MS. KOSKI:</p> <p>8 Q. Handing you what we marked as</p> <p>9 Exhibit 32. And for the record, this is a</p> <p>10 document with a Bates number</p> <p>11 ALLERGAN_MDL_03952959.</p> <p>12 And if you look on the second</p> <p>13 page of this document, this an e-mail -- just</p> <p>14 for the record, this is an e-mail that you wrote</p> <p>15 in July of 2007.</p> <p>16 Do you see that?</p> <p>17 A. Yes.</p> <p>18 Q. Okay. And on the second page, in</p> <p>19 the first full paragraph, do you see there that</p> <p>20 it says Mr. Mapes.</p> <p>21 Do you know who Mr. Mapes is?</p> <p>22 A. Yes, he was at DEA headquarters.</p> <p>23 Q. And you see the reference</p> <p>24 there -- and he worked at DEA, right?</p>	<p style="text-align: right;">Page 624</p> <p>1 MR. BUCHANAN: Objection,</p> <p>2 misstates the document, form.</p> <p>3 THE WITNESS: That is what it</p> <p>4 states later in the document, yes.</p> <p>5 BY MS. KOSKI:</p> <p>6 Q. And does that refresh your</p> <p>7 recollection about what was happening in 2007?</p> <p>8 MR. BUCHANAN: Objection to form.</p> <p>9 THE WITNESS: Yes.</p> <p>10 BY MS. KOSKI:</p> <p>11 Q. And did Anda accept Mr. Mapes'</p> <p>12 invitation to meet?</p> <p>13 A. Yes.</p> <p>14 Q. Now, do you recall when after</p> <p>15 Mr. Mapes contacted you you went in to meet with</p> <p>16 him?</p> <p>17 A. I do not.</p> <p>18 Q. Was it immediate?</p> <p>19 A. I'm assuming it was close to the</p> <p>20 date, but I don't know exactly when.</p> <p>21 (Document marked for</p> <p>22 identification as Par-Norton Deposition</p> <p>23 Exhibit No. 33.)</p> <p>24 BY MS. KOSKI:</p>

20 (Pages 621 to 624)

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<p style="text-align: right;">Page 625</p> <p>1 Q. Handing you what we've marked as</p> <p>2 Exhibit 33. For the record, Exhibit 33 is Bates</p> <p>3 number Anda_Opioids_MDL_0000152278.</p> <p>4 MR. BUCHANAN: I only have one</p> <p>5 page.</p> <p>6 MS. KOSKI: It's just a one-page</p> <p>7 document.</p> <p>8 MR. BUCHANAN: Oh, I'm sorry. I</p> <p>9 thought you were holding two, and it's</p> <p>10 Exhibit Number 33.</p> <p>11 MS. KOSKI: Thirty-three, yes.</p> <p>12 BY MS. KOSKI:</p> <p>13 Q. And you see this is an e-mail</p> <p>14 dated August 22nd, 2007?</p> <p>15 A. Yes.</p> <p>16 Q. Okay. And on the first line it</p> <p>17 says "Hello All, tomorrow's (8/23) meeting with</p> <p>18 the DEA."</p> <p>19 Do you see that?</p> <p>20 A. Yes, I do.</p> <p>21 Q. Okay. So is it fair to say the</p> <p>22 meeting was on August 23rd?</p> <p>23 A. Yes.</p> <p>24 Q. About a month after the phone</p>	<p style="text-align: right;">Page 627</p> <p>1 Q. -- and your testimony yesterday?</p> <p>2 Okay. Now, you had, as indicated</p> <p>3 in Exhibit 32, several calls with Mr. Mapes</p> <p>4 before the August 23rd meeting.</p> <p>5 Do you recall that?</p> <p>6 MR. BUCHANAN: Objection to form</p> <p>7 and the leading.</p> <p>8 THE WITNESS: I do not.</p> <p>9 BY MS. KOSKI:</p> <p>10 Q. Okay. If you look at Exhibit 32,</p> <p>11 you can see there's references to a number of</p> <p>12 phone calls if you read through the e-mail?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. Does that refresh your</p> <p>15 recollection that you had several phone calls</p> <p>16 with Mr. Mapes before the August 23rd meeting?</p> <p>17 MR. BUCHANAN: Objection to the</p> <p>18 form and the leading.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MS. KOSKI:</p> <p>21 Q. And the exhibit -- sorry -- 32 is</p> <p>22 a rather lengthy e-mail, Exhibit 32.</p> <p>23 Is it fair to characterize that</p> <p>24 as your notes from those phone calls, or how</p>
<p style="text-align: right;">Page 626</p> <p>1 call referenced in the prior exhibit?</p> <p>2 A. Yes.</p> <p>3 Q. And do you recall that the</p> <p>4 meeting was scheduled for about a two-hour time</p> <p>5 period with DEA?</p> <p>6 A. I'm not sure.</p> <p>7 Q. Do you recall it being a full day</p> <p>8 meeting?</p> <p>9 A. No, it was not.</p> <p>10 Q. And if you look at what we marked</p> <p>11 as Exhibit 33, you'll see again the first line,</p> <p>12 the meeting is scheduled from 12:00 to 2:00 p.m.</p> <p>13 Do you see that?</p> <p>14 A. Yes.</p> <p>15 Q. Is that consistent with your</p> <p>16 memory of the meeting?</p> <p>17 A. Yes.</p> <p>18 Q. Now, referring back to Exhibit 2,</p> <p>19 you wrote that DEA asked for the meeting because</p> <p>20 of Anda's, and I think I'm quoting you here,</p> <p>21 "lack of a robust SOM program."</p> <p>22 Do you recall that from the</p> <p>23 document --</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 628</p> <p>1 would you characterize what's in that e-mail?</p> <p>2 A. That is documentation of the</p> <p>3 phone calls.</p> <p>4 Q. Okay. And, again, focusing on --</p> <p>5 I think now we're on the -- if you look at the</p> <p>6 bottom of Exhibit 32, you'll see the paragraph</p> <p>7 starts on July 16, 2007.</p> <p>8 Do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. It says "I received a telephone</p> <p>11 call from Michael Mapes, DEA HQ."</p> <p>12 Do you see that?</p> <p>13 A. Yes.</p> <p>14 MR. BUCHANAN: I don't, actually.</p> <p>15 Can you just highlight on Bates 60?</p> <p>16 MS. KOSKI: On page 59 and it's</p> <p>17 below the sort of the page break line,</p> <p>18 the first page of the e-mail.</p> <p>19 Do you see that, Exhibit 32?</p> <p>20 MR. BUCHANAN: Can you see it?</p> <p>21 Thank you. I got it. Thank you.</p> <p>22 BY MS. KOSKI:</p> <p>23 Q. Do you see that reference to</p> <p>24 Mr. Mapes?</p>

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<p style="text-align: right;">Page 629</p> <p>1 A. Yes.</p> <p>2 Q. And so, according to this note,</p> <p>3 you, Ms. Hernandez received a call from</p> <p>4 Mr. Mapes, right?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. I believe you testified</p> <p>7 yesterday that part of the reason you were</p> <p>8 involved was because you knew the people at DEA</p> <p>9 that were involved?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And, in fact, this</p> <p>12 document indicates that the initial contact came</p> <p>13 directly to you; is that right?</p> <p>14 A. Yes, it did.</p> <p>15 Q. And if you look at the next</p> <p>16 paragraph, there's a reference there that</p> <p>17 Mr. Mapes told you DEA had seen "a steady</p> <p>18 increase in Anda sales of hydrocodone," right?</p> <p>19 That's at the bottom of the page going over to</p> <p>20 the next page.</p> <p>21 A. Yes.</p> <p>22 Q. And then you note, we don't need</p> <p>23 to read through it all, but you note a number of</p> <p>24 other things that you talked about with</p>	<p style="text-align: right;">Page 631</p> <p>1 leading.</p> <p>2 THE WITNESS: I did not have any</p> <p>3 knowledge of Anda orders at the time. I</p> <p>4 was just documenting what was told to me</p> <p>5 by Mr. Mapes.</p> <p>6 BY MS. KOSKI:</p> <p>7 Q. Okay. That's because Anda had a</p> <p>8 compliance department, right?</p> <p>9 MR. BUCHANAN: Objection to form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. KOSKI:</p> <p>12 Q. And you didn't work in it?</p> <p>13 A. Correct.</p> <p>14 Q. Okay. And then if you see in the</p> <p>15 last paragraph where you say this commitment was</p> <p>16 conveyed to Mr. Mapes by telephone on 7/16/2007.</p> <p>17 Do you see that?</p> <p>18 A. Yes.</p> <p>19 Q. So you called Mr. Mapes back</p> <p>20 after you spoke with some of the folks at Anda,</p> <p>21 right?</p> <p>22 A. Yes.</p> <p>23 Q. And that's referenced in this</p> <p>24 document, right?</p>
<p style="text-align: right;">Page 630</p> <p>1 Mr. Mapes during that initial call, right?</p> <p>2 A. Yes.</p> <p>3 Q. And then the bottom paragraph --</p> <p>4 oh, I'm sorry, in that same -- sorry, the top</p> <p>5 paragraph, you indicate that Mr. Mapes asked</p> <p>6 about the effectiveness of Anda's suspicious</p> <p>7 order monitoring program or system, excuse me.</p> <p>8 Do you see that, the top of the</p> <p>9 page marked 60?</p> <p>10 A. No, I'm sorry, I don't see where.</p> <p>11 Q. The paragraph that bleeds over</p> <p>12 from the first to the second page, and you'll</p> <p>13 see he says, "He also asked about the</p> <p>14 effectiveness of Anda's suspicious order</p> <p>15 monitoring system; quoting orders of 279,000</p> <p>16 hydrocodone dosage units sold to a single</p> <p>17 customer in a 30 day period and another for</p> <p>18 174,000."</p> <p>19 Do you see that?</p> <p>20 A. Yes, I see that.</p> <p>21 Q. And so did you understand this is</p> <p>22 in reference to two specific orders that Anda</p> <p>23 had filled?</p> <p>24 MR. BUCHANAN: Objection to the</p>	<p style="text-align: right;">Page 632</p> <p>1 A. Mm-hmm, yes.</p> <p>2 (Document marked for</p> <p>3 identification as Par-Norton Deposition</p> <p>4 Exhibit No. 34.)</p> <p>5 BY MS. KOSKI:</p> <p>6 Q. Handing you what we marked as</p> <p>7 Exhibit 34.</p> <p>8 MS. KOSKI: Counsel. And for the</p> <p>9 record, Exhibit 34 is Bates</p> <p>10 Anda_Opioids_MDL_0000275627.</p> <p>11 BY MS. KOSKI:</p> <p>12 Q. Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Okay. And what's this document?</p> <p>15 A. It's an internal e-mail from</p> <p>16 myself to Diane Miranda and Al Paonessa.</p> <p>17 Q. With a CC to Michael Cochrane and</p> <p>18 Patrick Cochrane?</p> <p>19 A. Yes.</p> <p>20 Q. And what's the date on it?</p> <p>21 A. July 31st, 2007.</p> <p>22 Q. Okay. And the subject is "DEA</p> <p>23 Teleconference re: CS Distribution/Anda."</p> <p>24 Do you see that?</p>

22 (Pages 629 to 632)

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<p style="text-align: right;">Page 633</p> <p>1 A. Yes.</p> <p>2 Q. Okay. And is it -- and the first</p> <p>3 reference there is "today we finally got to have</p> <p>4 our teleconference with DEA."</p> <p>5 Do you see that?</p> <p>6 A. Yes.</p> <p>7 Q. So the today referenced there</p> <p>8 would be the date of the e-mail; is that fair?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. So this is, in fact, a</p> <p>11 third call you had with DEA relating to the Anda</p> <p>12 issues?</p> <p>13 A. It is another call, yes.</p> <p>14 Q. Okay. And you made notes of that</p> <p>15 call as well, right?</p> <p>16 A. Yes.</p> <p>17 Q. And that's reflected in what we</p> <p>18 just marked as Exhibit 34?</p> <p>19 A. Yes.</p> <p>20 Q. And these notes were made the</p> <p>21 same day as the phone call, right?</p> <p>22 A. Yes.</p> <p>23 Q. Fair to say it would have been</p> <p>24 fresh in your memory at the time that you wrote</p>	<p style="text-align: right;">Page 635</p> <p>1 interaction you indicated that after or during</p> <p>2 your discussions with DEA, Anda made some</p> <p>3 changes to its SOMS program, right?</p> <p>4 A. Yes.</p> <p>5 Q. Okay. And I think you referred</p> <p>6 to a limit, but I don't know that you put a</p> <p>7 number on it.</p> <p>8 A. Yes.</p> <p>9 Q. Okay. Does this refresh your</p> <p>10 recollection about the number?</p> <p>11 A. It does.</p> <p>12 Q. Okay. And you also discuss other</p> <p>13 things or you reflect your discussion with</p> <p>14 Mr. Mapes about other things as well here in</p> <p>15 Exhibit 34, and you discussed two customers in</p> <p>16 particular who had -- whose legitimate needs</p> <p>17 dictate quantities greater than 5,000 a month.</p> <p>18 Do you see that?</p> <p>19 A. Yes, I do.</p> <p>20 Q. And that's a reflection of the</p> <p>21 discussion that Anda had with Mr. Mapes on</p> <p>22 July 31st of 2007?</p> <p>23 A. Yes.</p> <p>24 Q. And then you say here, "His exact</p>
<p style="text-align: right;">Page 634</p> <p>1 the e-mail?</p> <p>2 A. Yes.</p> <p>3 Q. And as reflected in this e-mail,</p> <p>4 you discussed Anda's decision to establish new</p> <p>5 limits on customers who purchase controlled</p> <p>6 substances from Anda, right, beginning of the</p> <p>7 second paragraph. You need reference?</p> <p>8 A. Yes, it talks about limits.</p> <p>9 Q. Right, and that's Anda's decision</p> <p>10 to establish the new limits, right?</p> <p>11 MR. BUCHANAN: Objection to form.</p> <p>12 BY MS. KOSKI:</p> <p>13 Q. We're talking about Anda here?</p> <p>14 A. Yes.</p> <p>15 Q. And the new limit was 5,000</p> <p>16 dosage units per drug family.</p> <p>17 Do you see that?</p> <p>18 A. For hydrocodone products, yes.</p> <p>19 Q. And other controlled substances</p> <p>20 with a high diversion potential.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And yesterday you referred</p> <p>24 to and you were talking about your -- this</p>	<p style="text-align: right;">Page 636</p> <p>1 words were that '5,000 dosage units is not a</p> <p>2 hard limit, but a start' and that as long as we</p> <p>3 are making the effort to know the customer's</p> <p>4 business he is fine with that."</p> <p>5 Do you see that reference?</p> <p>6 A. I do.</p> <p>7 Q. And that's reflecting your</p> <p>8 conversation at the time with Mr. Mapes, right?</p> <p>9 A. Yes.</p> <p>10 Q. And if you refer back to I</p> <p>11 believe it's Exhibit 32 or in your first call,</p> <p>12 you indicate that Mr. Mapes had expressly</p> <p>13 referred to some specific large orders as the</p> <p>14 reason -- one of the reasons, at least, for the</p> <p>15 phone call that he made to you, right?</p> <p>16 A. Yes.</p> <p>17 Q. And so here on July 31st, you're</p> <p>18 discussing -- you reflect -- you're reflecting</p> <p>19 your discussion with Mr. Mapes where you talked</p> <p>20 about that, the large order situation, fair?</p> <p>21 MR. BUCHANAN: Object to the</p> <p>22 leading.</p> <p>23 THE WITNESS: Without knowing the</p> <p>24 customers, I'm not sure if that's the</p>

23 (Pages 633 to 636)

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<p style="text-align: right;">Page 637</p> <p>1 same, but there is -- there are comments</p> <p>2 here, yes.</p> <p>3 BY MS. KOSKI:</p> <p>4 Q. And the idea being that for some</p> <p>5 specific customers, dispensing more than the</p> <p>6 5,000 per month that was recommended by DEA</p> <p>7 could be appropriate, right?</p> <p>8 MR. BUCHANAN: Objection to the</p> <p>9 form.</p> <p>10 THE WITNESS: Yes.</p> <p>11 BY MS. KOSKI:</p> <p>12 Q. And that's reflected in your</p> <p>13 notes that you wrote at the time, right?</p> <p>14 MR. BUCHANAN: Objection to the</p> <p>15 form.</p> <p>16 THE WITNESS: Yes, that's based</p> <p>17 on the comments from DEA.</p> <p>18 BY MS. KOSKI:</p> <p>19 Q. If you look back to 32, and this</p> <p>20 was the e-mail we were just looking at that</p> <p>21 referred to the initial phone call you received</p> <p>22 from Mr. Mapes, right?</p> <p>23 A. Yes.</p> <p>24 Q. And if you see on the second page</p>	<p style="text-align: right;">Page 639</p> <p>1 to the actions taken against Southwood,</p> <p>2 Bellco, Richie, those companies?</p> <p>3 BY MS. KOSKI:</p> <p>4 Q. Right, right.</p> <p>5 A. Yes.</p> <p>6 Q. So you refer -- you refer here in</p> <p>7 your notes to recent regulatory actions DEA has</p> <p>8 taken, right?</p> <p>9 A. Yes.</p> <p>10 Q. And we talked earlier this</p> <p>11 morning about some of the types of regulatory</p> <p>12 actions that DEA is empowered to take, right?</p> <p>13 A. Yes.</p> <p>14 Q. And did you understand that's</p> <p>15 what Mr. Mapes was referring to with respect to</p> <p>16 these other companies?</p> <p>17 MR. BUCHANAN: Objection to form.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MS. KOSKI:</p> <p>20 Q. Now, DEA never instituted any</p> <p>21 formal action against Anda while you worked at</p> <p>22 Anda, right?</p> <p>23 MR. BUCHANAN: Objection to form.</p> <p>24 MS. KOSKI: Excuse me. Strike</p>
<p style="text-align: right;">Page 638</p> <p>1 of the document, there's a reference in your</p> <p>2 notes about what -- that Mr. Mapes, I believe is</p> <p>3 the he, referenced recent regulatory actions DEA</p> <p>4 has taken against, and he names some entities,</p> <p>5 not Anda, right?</p> <p>6 A. Yes.</p> <p>7 Q. Okay. And you recorded that in</p> <p>8 these notes from your conversation with him at</p> <p>9 the time?</p> <p>10 A. I did.</p> <p>11 Q. Now, when we talked earlier about</p> <p>12 DEA has different mechanisms of communicating</p> <p>13 with the industry, DEA has different formal</p> <p>14 processes they could take, did you understand</p> <p>15 that was what Mr. Mapes was referencing here in</p> <p>16 this document?</p> <p>17 MR. BUCHANAN: Objection to the</p> <p>18 form. Which document are you</p> <p>19 referencing, counsel?</p> <p>20 MS. KOSKI: Exhibit 32 that you</p> <p>21 have in your hand.</p> <p>22 MR. BUCHANAN: Objection to form,</p> <p>23 vague.</p> <p>24 THE WITNESS: Are you referring</p>	<p style="text-align: right;">Page 640</p> <p>1 that.</p> <p>2 BY MS. KOSKI:</p> <p>3 Q. DEA never instituted any formal</p> <p>4 action against Anda while you worked at Watson,</p> <p>5 right?</p> <p>6 A. Not that I'm aware of.</p> <p>7 Q. Instead, you -- this experience</p> <p>8 that you had with Mr. Mapes was a series of</p> <p>9 telephone calls and an agreed meeting; is that</p> <p>10 fair?</p> <p>11 A. Yes.</p> <p>12 Q. And I believe you discussed</p> <p>13 yesterday and maybe earlier this morning the</p> <p>14 distributor initiative that you believe this</p> <p>15 related to?</p> <p>16 MR. BUCHANAN: Objection to form</p> <p>17 and the leading.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MS. KOSKI:</p> <p>20 Q. And, in fact, during your</p> <p>21 conversations, you had an exchange of</p> <p>22 information with Mr. Mapes; is that fair?</p> <p>23 A. Yes.</p> <p>24 Q. And when we talked earlier about</p>

24 (Pages 637 to 640)

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<p style="text-align: right;">Page 641</p> <p>1 guidance received from DEA, would this fall into</p> <p>2 what you've referred to over the course of the</p> <p>3 couple days as guidance?</p> <p>4 A. Yes.</p> <p>5 Q. And, in fact, outside of this</p> <p>6 narrow context with Anda, you've had other</p> <p>7 occasions to have conversations with DEA, right?</p> <p>8 A. Yes.</p> <p>9 Q. And then just looking back at</p> <p>10 Exhibit 2 quickly, which is your employment</p> <p>11 application, for lack of a better word, do you</p> <p>12 have that Exhibit 2, the e-mail with your</p> <p>13 resume? Of course, it's at the bottom of the</p> <p>14 pile. It's at the bottom of the pile.</p> <p>15 A. Yes.</p> <p>16 Q. And do you see in there that you</p> <p>17 wrote that the meeting was for cause?</p> <p>18 A. Yes.</p> <p>19 Q. And when we talked about DEA has</p> <p>20 formal actions, we talked at one point about</p> <p>21 orders to show cause. That's one of the formal</p> <p>22 processes, right?</p> <p>23 A. It is, yes.</p> <p>24 Q. And an order to show cause is</p>	<p style="text-align: right;">Page 643</p> <p>1 MR. BUCHANAN: Objection to form,</p> <p>2 misstates the evidence.</p> <p>3 THE WITNESS: Yes.</p> <p>4 MS. KOSKI: That's all I have.</p> <p>5 Thank you.</p> <p>6 THE WITNESS: Thank you.</p> <p>7 MR. BUCHANAN: Do any other</p> <p>8 defense counsel have questions? We can</p> <p>9 close the record -- close it on that. I</p> <p>10 have follow-up questions. Go off the</p> <p>11 record for a few minutes.</p> <p>12 THE VIDEOGRAPHER: The time is</p> <p>13 9:57. Off the record.</p> <p>14 (Brief recess.)</p> <p>15 THE VIDEOGRAPHER: The time is</p> <p>16 10:24 a.m. This begins DVD Number 2.</p> <p>17 We are back on the record.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Ms. Norton, I have a few</p> <p>20 questions in follow-up to the questions asked by</p> <p>21 Endo's counsel, Qualitest's counsel as well as</p> <p>22 Anda counsel.</p> <p>23 A. Yes.</p> <p>24 Q. Before I do that, though, can we</p>
<p style="text-align: right;">Page 642</p> <p>1 something that actually compels the registrant</p> <p>2 to appear before DEA, right?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. And you didn't mean to</p> <p>5 suggest in Exhibit 2, in your employment</p> <p>6 application documents, that DEA issued an order</p> <p>7 to show cause to Anda, right?</p> <p>8 A. They did not.</p> <p>9 Q. In fact, they didn't do that,</p> <p>10 right?</p> <p>11 A. Correct.</p> <p>12 Q. And as long as you worked at</p> <p>13 Watson, you weren't aware of any occasion in</p> <p>14 which DEA issued Anda an order to show cause,</p> <p>15 right?</p> <p>16 A. I'm not aware of any.</p> <p>17 MR. BUCHANAN: Objection to the</p> <p>18 leading, move to strike.</p> <p>19 BY MS. KOSKI:</p> <p>20 Q. And, again, as we've gone through</p> <p>21 your contemporaneous notes from August of 2007,</p> <p>22 when the meeting happened, the meeting was a</p> <p>23 result of some exchanges between Anda and DEA</p> <p>24 and an invitation from you, right?</p>	<p style="text-align: right;">Page 644</p> <p>1 agree that you and I hadn't met before today?</p> <p>2 A. We met yesterday.</p> <p>3 Q. That's fair. Before your</p> <p>4 deposition began, we can agree on that?</p> <p>5 A. Yes.</p> <p>6 Q. Thank you. Obviously, you told</p> <p>7 us that you had an opportunity to meet with</p> <p>8 counsel for Endo, I think, before your testimony</p> <p>9 yesterday, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Three days?</p> <p>12 A. Yes.</p> <p>13 Q. Multiple hours each time?</p> <p>14 A. Yes.</p> <p>15 Q. Did you have an opportunity to</p> <p>16 meet with Anda's counsel before you answered</p> <p>17 questions today?</p> <p>18 A. Briefly by phone.</p> <p>19 Q. And in that regard, did you</p> <p>20 review or discuss documents to refresh your</p> <p>21 recollection?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. And what were they?</p> <p>24 MS. KOSKI: Objection.</p>




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<p style="text-align: right;">Page 645</p> <p>1 MS. LEIBELL: Objection. 2 BY MR. BUCHANAN: 3 Q. Did they refresh your 4 recollection? 5 A. Yes. 6 Q. What were they? 7 A. The Mike Mapes' phone call, 8 documentation of the first phone call. 9 Q. Okay. So you worked through that 10 document? 11 A. The first one, yes. 12 Q. Before you came in today? 13 A. Yes. 14 Q. Did you do that again before you 15 testified this morning? 16 A. No. 17 Q. Okay. Any other documents that 18 refreshed your recollection? 19 A. No. 20 Q. Okay. I'd like now to start, and 21 we'll get to the Anda portion of this. I'd like 22 to start with your testimony relating to your 23 time at Qualitest. 24 You joined in 2011, you left in</p>	<p style="text-align: right;">Page 647</p> <p>1 Q. Also incorporated at some point 2 in time after 2013, consideration of IMS data, 3 correct? 4 A. I don't know the exact date as to 5 when it was implemented. That was before -- I 6 don't know exact date, but 2013, yes. 7 Q. Yeah, we looked at documents in 8 early 2013 where you said we need to start 9 incorporating IMS data. 10 Do you recall that? 11 A. Yes. 12 Q. So you hadn't been doing it prior 13 to 2013, correct? 14 MS. VANNI: Object to form. 15 THE WITNESS: We had IMS data. 16 This was different data. 17 BY MR. BUCHANAN: 18 Q. Yeah, I'm referring to IMS data 19 so that you could evaluate your customer 20 thresholds or customer levels to see whether 21 they were buying above or below national 22 averages for classes of trade? 23 A. Yes, correct. 24 Q. You were not doing that prior to</p>
<p style="text-align: right;">Page 646</p> <p>1 2014, right? 2 A. Yes. 3 Q. You were asked some general 4 questions, I think open-ended questions about 5 describe your SOM process. 6 Do you recall those questions on 7 examination by Endo counsel? 8 A. Yes. 9 Q. Okay. And you gave a list of 10 things that were done. You would look at order 11 of interests. You would look at the customer's 12 specific history, look at the customer 13 questionnaire. You would get customer feedback. 14 You would go and visit customers. You would do 15 that whole process. 16 Do you recall that? 17 A. Yes. 18 Q. That process was implemented, if 19 I understand your testimony correctly, in 2013? 20 A. Over time. 21 Q. The process you described with 22 those items that I just listed, that was the 23 process in place as of 2013, correct? 24 A. It was, yes.</p>	<p style="text-align: right;">Page 648</p> <p>1 2013, correct? 2 A. No. 3 Q. I'm correct? 4 A. Yes, you are correct. 5 Q. Thank you. We talked yesterday 6 about the incorporation of chargeback data into 7 the process and looked at some correspondence 8 where Mr. Brantley was using chargeback data in 9 connection with his correspondence with your 10 direct customers to talk about issues with 11 customers of customers. 12 Do you recall that? 13 A. Yes, I do. 14 Q. Use of chargeback data was not 15 being done prior to 2013, correct? 16 A. Correct. 17 Q. And we looked at documents 18 yesterday where, in your own words, you said you 19 needed to revamp the SOM process in 2013, 20 correct? 21 A. Yes. 22 Q. And we further looked at 23 documents yesterday where you were told in 2013 24 that your current SOM program systems and</p>


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<p style="text-align: right;">Page 649</p> <p>1 procedures do not meet the regulatory</p> <p>2 requirements.</p> <p>3 Do you recall that?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: I'm not sure what</p> <p>6 document it was.</p> <p>7 BY MR. BUCHANAN:</p> <p>8 Q. E-15, I'm sorry, Exhibit 15, it's</p> <p>9 E1052. Can we go to 1052.1. I don't have the</p> <p>10 exhibits to give you. There's a stack right</p> <p>11 there.</p> <p>12 All right. Let's -- we see this</p> <p>13 correspondence between yourself and Ms. Connell,</p> <p>14 your boss at the time?</p> <p>15 A. Yes, correct.</p> <p>16 Q. Okay. It says, "Jill, I added</p> <p>17 the action items and the estimated completion.</p> <p>18 If Judy can put them in the Gantt chart it would</p> <p>19 be a big help. Again, the dates are estimates</p> <p>20 since input is needed from other departments to</p> <p>21 confirm."</p> <p>22 This is an e-mail from yourself</p> <p>23 to your boss in 2013, again before you sat down</p> <p>24 with DEA, correct?</p>	<p style="text-align: right;">Page 651</p> <p>1 the consultant opinion, we can look at yours as</p> <p>2 of the same time. Exhibit 16, could we please</p> <p>3 go to E.1071.</p> <p>4 And here we have, ma'am, a</p> <p>5 presentation you put together for Ms. Connell</p> <p>6 around the same period of time, February 2013.</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. I'm on the cover letter right</p> <p>10 now.</p> <p>11 A. Yes.</p> <p>12 Q. Okay. And you were putting</p> <p>13 together action items and things that needed to</p> <p>14 be done and to address various compliance issues</p> <p>15 you were having at that time, correct?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: Improvements that</p> <p>18 we wanted to make, not compliance</p> <p>19 issues.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 </p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 650</p> <p>1 A. Correct.</p> <p>2 Q. Some consultants had come in and</p> <p>3 looked at your systems, spent a couple days on</p> <p>4 site looking at things, correct?</p> <p>5 A. Yes.</p> <p>6 Q. All right. Could we go to .3.</p> <p>7 </p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Fair enough. Could you look at</p> <p>23 Exhibit 16, ma'am.</p> <p>24 And we don't have to just look at</p>	<p style="text-align: right;">Page 652</p> <p>1 </p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p style="text-align: right;">Page 653</p> <p>1 </p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18 Can you pull up Exhibit 4, and for the video --</p> <p>19 excuse me for the display screens, it's E1157.1.</p> <p>20 As of 2011 -- was your testimony</p> <p>21 yesterday that 70% of the company's business was</p> <p>22 controlled substances, ma'am?</p> <p>23 A. I said approximately. I didn't</p> <p>24 know exact.</p>	<p style="text-align: right;">Page 655</p> <p>1 and for the years prior, we could agree the</p> <p>2 company was making billions and billions and</p> <p>3 billions of controlled substances that were</p> <p>4 entering the market, correct?</p> <p>5 MS. VANNI: Object to the form.</p> <p>6 THE WITNESS: Again, I can't</p> <p>7 speak to the data or to things that</p> <p>8 happened before I arrived.</p> <p>9 MR. BUCHANAN: Okay. I mean,</p> <p>10 this is a bit of a challenge because</p> <p>11 defense counsel has pointed us to what</p> <p>12 I'm now going to mark as Exhibit 35.</p> <p>13 Is that correct, 35 is next in</p> <p>14 order?</p> <p>15 (Document marked for</p> <p>16 identification as Par-Norton Deposition</p> <p>17 Exhibit No. 35.)</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Passing you, ma'am, Exhibit 35.</p> <p>20 There you go. And I'll represent to you, ma'am,</p> <p>21 that the summary table that was presented to you</p> <p>22 was derived from these spreadsheets that defense</p> <p>23 counsel provided to us.</p> <p>24 I guess what I'd like to -- what</p>
<p style="text-align: right;">Page 654</p> <p>1 Q. Okay. As of 2011 we see -- what</p> <p>2 is that, over 2 billion controlled substances?</p> <p>3 A. Again, I can't speak to the</p> <p>4 detail of this document. I don't know what went</p> <p>5 into it.</p> <p>6 Q. Okay. We could agree the company</p> <p>7 made a lot of controlled substances, right?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: They were in the</p> <p>10 controlled substance business.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Right, and as a company in the</p> <p>13 controlled substance business, they had one</p> <p>14 person in DEA compliance; is that right?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: At the time, yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. When you were hired as of 2011.</p> <p>19 MR. BUCHANAN: Can you take that</p> <p>20 down. Can you blow out 2008 through</p> <p>21 2011 with the legend on the left with</p> <p>22 drugs and years.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. And so for 2011, when you joined,</p>	<p style="text-align: right;">Page 656</p> <p>1 I'd like to understand, ma'am, is in 2008 how</p> <p>2 many hydrocodone APAP did Qualitest ship?</p> <p>3 A. Again, I don't know where this</p> <p>4 data came from. I don't know how it was pulled</p> <p>5 for research, and I wasn't here in 2008 to speak</p> <p>6 to it.</p> <p>7 Q. I take it you're familiar with</p> <p>8 this type of form, correct?</p> <p>9 A. I am not familiar with this type</p> <p>10 of form.</p> <p>11 Q. Okay. As the head of DEA</p> <p>12 compliance, did you review data on the quantity</p> <p>13 of pills the company was shipping?</p> <p>14 A. We had to do reports that gave</p> <p>15 accountability of what we were shipping, yes.</p> <p>16 Q. Did you get them in a more user</p> <p>17 friendly form than this?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: Yes.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. You did?</p> <p>22 A. Well, some of it, sometimes.</p> <p>23 Q. You could get your data and</p> <p>24 systems team to identify for you the quantity of</p>

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<p style="text-align: right;">Page 657</p> <p>1 shipped material?</p> <p>2 A. Not all. Different things were</p> <p>3 in different systems.</p> <p>4 Q. If you wanted to get the quantity</p> <p>5 of sales to customers could you get that, ma'am?</p> <p>6 A. Depends on what is called sales.</p> <p>7 So are -- if we're referring to direct shipment</p> <p>8 to customer, we could get some information, yes,</p> <p>9 more information after SAP was implemented, but</p> <p>10 not at first.</p> <p>11 Q. I assume the company kept track</p> <p>12 of the drugs that it was selling to its</p> <p>13 customers?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Company had systems to do</p> <p>16 that?</p> <p>17 A. Systems and electronic -- some</p> <p>18 electronic, some manual.</p> <p>19 Q. And we've had computers for a</p> <p>20 long time, right?</p> <p>21 A. Yes, we have.</p> <p>22 Q. Okay. So as of matter of</p> <p>23 processing large volumes of orders, the company</p> <p>24 had a computer system, correct?</p>	<p style="text-align: right;">Page 659</p> <p>1 with the witness.</p> <p>2 MS. VANNI: I appreciate that</p> <p>3 because it is marked highly</p> <p>4 confidential.</p> <p>5 MR. BUCHANAN: It's from the</p> <p>6 witness' time at the company, so I</p> <p>7 believe it's an appropriate use, but I'm</p> <p>8 being sensitive to whatever concerns you</p> <p>9 may have on its distribution. You can</p> <p>10 address that with your co-counsel --</p> <p>11 co-defense counsel at a later point in</p> <p>12 time. I am not burning it into the</p> <p>13 video feed.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Looking through it, ma'am, could</p> <p>16 you please, what I've identified as Exhibit --</p> <p>17 was that 38 -- 35, could you tell us, please,</p> <p>18 the shipments for hydrocodone products in 2011?</p> <p>19 A. I'm sorry, I can't read it. It's</p> <p>20 very small.</p> <p>21 Q. I'll give you some time to see if</p> <p>22 you can sum that up or give us a number.</p> <p>23 A. I don't see a total. I see line</p> <p>24 items.</p>
<p style="text-align: right;">Page 658</p> <p>1 A. For some things, yes.</p> <p>2 Q. For keeping track of shipments to</p> <p>3 customers, correct?</p> <p>4 A. Parts of that data, yes.</p> <p>5 Q. And keeping track of orders to</p> <p>6 customers, correct?</p> <p>7 A. Parts of that data, yes.</p> <p>8 Q. Right. Well, just if you could,</p> <p>9 ma'am, just look through this and please tell us</p> <p>10 the volume of hydrocodone APAP product that was</p> <p>11 shipped in your first year, 2011?</p> <p>12 MR. BUCHANAN: I'm sorry, please</p> <p>13 take that document down.</p> <p>14 MS. VANNI: Counsel, if you</p> <p>15 wouldn't mind, could you read the Bates</p> <p>16 number in. I saw it and now it sort of</p> <p>17 disappeared, and I don't know where it</p> <p>18 went.</p> <p>19 MR. BUCHANAN: You know what, I</p> <p>20 gave you a copy. I'll give you another</p> <p>21 one to take home. My paralegal does</p> <p>22 have an extra copy. I wasn't sure</p> <p>23 whether this was an appropriate one for</p> <p>24 broader distribution, so I'm giving it</p>	<p style="text-align: right;">Page 660</p> <p>1 Q. How about for oxycodone shipments</p> <p>2 in 2011, ma'am?</p> <p>3 A. I don't see totals on here. I</p> <p>4 just see line items, individual line items.</p> <p>5 Q. Would my question be easier to</p> <p>6 answer if I said orders?</p> <p>7 A. No, it would not.</p> <p>8 Q. How about orders of hydrocodone,</p> <p>9 orders of oxycodone, the quantities that you</p> <p>10 received in 2011?</p> <p>11 A. No. I mean, this is -- these are</p> <p>12 individual customer orders, by the looks of it.</p> <p>13 I don't know when they occurred, since I can't</p> <p>14 see the dates.</p> <p>15 Q. I just need the totals, ma'am.</p> <p>16 A. I can't. There's no -- I don't</p> <p>17 know where the totals are in here.</p> <p>18 Q. There was some question about the</p> <p>19 providence of the exhibit that we prepared and</p> <p>20 showed to you and you had questions about where</p> <p>21 things came from. I provided that to you.</p> <p>22 So my question now is can you</p> <p>23 give us the shipments of hydrocodone and</p> <p>24 oxycodone for the years that we're talking</p>

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<p style="text-align: right;">Page 661</p> <p>1 about?</p> <p>2 A. I cannot. What you provided me</p> <p>3 is a report that I can't read that I would need</p> <p>4 a considerable amount of time to go through in</p> <p>5 order to pull information out of, and I don't</p> <p>6 even know if it contains transfers or just</p> <p>7 financial transactions or what it contains, so I</p> <p>8 can't on the spot give you that information.</p> <p>9 Q. All great questions of the data.</p> <p>10 MR. BUCHANAN: Counsel, we'll</p> <p>11 take your stipulations as to all those</p> <p>12 numbers if you'll provide them kindly.</p> <p>13 Do you have them?</p> <p>14 MS. VANNI: Do I have what? Do I</p> <p>15 have the --</p> <p>16 MR. BUCHANAN: The information in</p> <p>17 the numbers the witness is asking for,</p> <p>18 because this is where you pointed us --</p> <p>19 I mean, I'm not comfortable with the</p> <p>20 witness questioning the providence of</p> <p>21 the data you've shown -- told us to go</p> <p>22 to look at, so I'll take your</p> <p>23 representations and stipulations as to</p> <p>24 what it is.</p>	<p style="text-align: right;">Page 663</p> <p>1 making a lot of hydrocodone and a lot of</p> <p>2 oxycodone in 2011 when you got to the company,</p> <p>3 right?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: The company was</p> <p>6 making hydrocodone and oxycodone. I</p> <p>7 don't want to define a lot. I don't</p> <p>8 know what we're comparing it to. It's</p> <p>9 been...</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Okay. Well, I'll ask you to stay</p> <p>12 with me on this, and I'll ask you to assume that</p> <p>13 the company was making billions of pills of</p> <p>14 oxycodone or hydrocodone per year. Is that a</p> <p>15 lot to you?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 THE WITNESS: That's opinion.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Okay. You gave opinions</p> <p>20 throughout the day.</p> <p>21 A. I have nothing to compare it to.</p> <p>22 I can't comment on what "a lot" is.</p> <p>23 Q. You don't have an opinion as to</p> <p>24 whether billions of hydrocodone pills, hundreds</p>
<p style="text-align: right;">Page 662</p> <p>1 MS. VANNI: I can't stipulate to</p> <p>2 anything. This was a document that I'm</p> <p>3 seeing for the first time today that</p> <p>4 you've presented to me in an illegible</p> <p>5 form. I don't know if this was prepared</p> <p>6 for purposes of litigation. I don't</p> <p>7 know what this document is. I</p> <p>8 apologize, but I can't stipulate to</p> <p>9 anything because I don't even know what</p> <p>10 it is. I can't even read it.</p> <p>11 MR. BUCHANAN: All good points</p> <p>12 you're raising, and I don't think it's</p> <p>13 any different in reverse on this side of</p> <p>14 the base, certainly, because we don't</p> <p>15 have the resources to confirm any of</p> <p>16 that information, but this is the</p> <p>17 spreadsheet you called to our attention</p> <p>18 as 33C in your rog responses.</p> <p>19 Okay. I'll move on at this</p> <p>20 point.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Ma'am, we were looking at 1071.8.</p> <p>23 We can agree, even though we can't pin down the</p> <p>24 actual numbers of pills, that the company was</p>	<p style="text-align: right;">Page 664</p> <p>1 of millions of oxycodone pills is a lot?</p> <p>2 A. No, I don't.</p> <p>3 MS. VANNI: Objection, asked and</p> <p>4 answered and argumentative.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. As the head of DEA compliance who</p> <p>7 was the person in charge of ensuring the</p> <p>8 adequacy of the company's SOMS system --</p> <p>9 A. Yes.</p> <p>10 Q. -- you don't have an opinion as</p> <p>11 to whether the company was making a lot --</p> <p>12 MS. VANNI: Objection.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. -- of oxycodone or hydrocodone?</p> <p>15 A. No, I don't have comparisons to</p> <p>16 other companies. I don't have -- no, I don't</p> <p>17 have an opinion.</p> <p>18 Q. Okay. Let's come back now to</p> <p>19 weaknesses of the company as of this 2013</p> <p>20 document. You had weaknesses related to DEA</p> <p>21 security and controls, right?</p> <p>22 A. Things I wanted to improve upon,</p> <p>23 yes.</p> <p>24 Q. What you wrote was weaknesses?</p>

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<p style="text-align: right;">Page 665</p> <p>1 A. That's what the document says.</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p>	<p style="text-align: right;">Page 667</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 about this meeting you had with DEA in March of</p> <p>5 2013, and you characterized it for us yesterday,</p> <p>6 perhaps recharacterized it today, but fair to</p> <p>7 say throughout the rest of 2013, the company got</p> <p>8 about trying to implement and strengthen its</p> <p>9 SOMS process, fair?</p> <p>10 MS. VANNI: Object to the</p> <p>11 colloquy. Object to form.</p> <p>12 THE WITNESS: We continued with</p> <p>13 our planned improvements.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Okay. And you also discussed</p> <p>16 with defense counsel on direct examination the</p> <p>17 quota process.</p> <p>18 Do you recall that?</p> <p>19 A. I do.</p> <p>20 Q. The inner relation with the DEA</p> <p>21 going back and forth from time to time, and you</p> <p>22 said that was an important part of your</p> <p>23 responsibilities?</p> <p>24 A. Yes, it is -- was.</p>
<p style="text-align: right;">Page 666</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p>	<p style="text-align: right;">Page 668</p> <p>1 MR. BUCHANAN: Could I have 1068,</p> <p>2 please. I need a copy for the witness.</p> <p>3 Could you take it down until I have</p> <p>4 copies for the witness, please.</p> <p>5 Counsel.</p> <p>6 (Document marked for</p> <p>7 identification as Par-Norton Deposition</p> <p>8 Exhibit No. 36.)</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. We're marking this, ma'am, as</p> <p>11 Exhibit 39 (sic) to your deposition.</p> <p>12 A. Okay.</p> <p>13 Q. It's an e-mail from -- e-mail</p> <p>14 exchange between you and a few other folks at</p> <p>15 Qualitest, Sanjay Patel, yourself as the latest</p> <p>16 in time e-mail at the top, but there's an</p> <p>17 exchange going on regarding a quota request.</p> <p>18 You can go bottom up, but I suggest you can</p> <p>19 probably get all the information you need on the</p> <p>20 first page if you start at the bottom of the</p> <p>21 first. We're at 1068.1, and you received an</p> <p>22 e-mail from Fang Zhou?</p> <p>23 A. Fang Zhou.</p> <p>24 Q. Zhou. "Hi, Tracey. Please find</p>



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<p style="text-align: right;">Page 669</p> <p>1 the information below to apply the quote of</p> <p>2 oxycodone hydrochloride for 2013. Would you</p> <p>3 apply quota for 115 kg oxycodone hydrocodone</p> <p>4 ASAP?"</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes, you did.</p> <p>7 Q. And then it's got a list of the</p> <p>8 various units and strengths.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. And is this generally the</p> <p>12 process, people throughout the organization with</p> <p>13 various needs, whether it was research, whether</p> <p>14 it was testing, whether it was sales for</p> <p>15 production, would come to you and give you</p> <p>16 numbers to apply to quota or to seek quota from</p> <p>17 DEA if you needed more?</p> <p>18 MS. VANNI: Objection to form.</p> <p>19 THE WITNESS: For sales that was</p> <p>20 not the process. We would look at our</p> <p>21 sales using IMS data, and we would -- we</p> <p>22 would submit quota using that</p> <p>23 information. This is for research, and</p> <p>24 in the research case, they will tell us</p>	<p style="text-align: right;">Page 671</p> <p>1 not sure asking for this in our current SOMS</p> <p>2 environment, and your current SOMS environment</p> <p>3 in early 2013, two months after you met with the</p> <p>4 DEA, was a SOMS environment that you</p> <p>5 characterized as weak and inadequate, right?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: In that prior</p> <p>8 document, that's how it was</p> <p>9 characterized.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. That's right.</p> <p>12 And what you noted here is you</p> <p>13 were, I guess, seeking input from your</p> <p>14 colleague, Mr. Patel, was not sure asking for</p> <p>15 this, and "this" would be a quota increase,</p> <p>16 right?</p> <p>17 A. Yes.</p> <p>18 Q. "Not sure asking for this in the</p> <p>19 company's current SOMS environment is the best</p> <p>20 idea."</p> <p>21 Did I read that correctly?</p> <p>22 A. Yes, you did.</p> <p>23 Q. Thank you. You can set that</p> <p>24 aside.</p>
<p style="text-align: right;">Page 670</p> <p>1 how much we need -- how much they need,</p> <p>2 and it's our job to push back on that</p> <p>3 quantity and to determine if that</p> <p>4 actually is definitively needed.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. And so this is all</p> <p>7 happening in mid-2013 a few months after your --</p> <p>8 May 2013, a few months after your meeting with</p> <p>9 DEA, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Two months exactly.</p> <p>12 And your response is you forward</p> <p>13 this to Mr. Patel is FYI, I guess you are</p> <p>14 forwarding the thread to him for consideration?</p> <p>15 A. Yes.</p> <p>16 Q. FYI, for your information, is</p> <p>17 that what that means?</p> <p>18 A. Yes, uh-huh.</p> <p>19 Q. "Not sure asking for this in" --</p> <p>20 what did you write?</p> <p>21 A. "Not sure asking for this in our</p> <p>22 current SOMS environment is the best idea.</p> <p>23 Thoughts?"</p> <p>24 Q. Okay. Let's pause on that. So</p>	<p style="text-align: right;">Page 672</p> <p>1 You talked about some of the SOMS</p> <p>2 processes the company engaged in in this 2013</p> <p>3 and later period, consideration of information</p> <p>4 and how that worked.</p> <p>5 You also formed a SOMS advisory</p> <p>6 board, right?</p> <p>7 A. Yes, we did.</p> <p>8 Q. Okay.</p> <p>9 MR. BUCHANAN: Could I have 1148.</p> <p>10 This will be Exhibit 43. Can we go off</p> <p>11 the record.</p> <p>12 THE VIDEOGRAPHER: The time is</p> <p>13 10:48. Off the record.</p> <p>14 (Document marked for</p> <p>15 identification as Par-Norton Deposition</p> <p>16 Exhibit No. 37.)</p> <p>17 THE VIDEOGRAPHER: The time is</p> <p>18 10:50 a.m. We are back on the record.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. Passing you, ma'am, what we just</p> <p>21 marked as Exhibit 37 to your record. Our</p> <p>22 internal number is E1148. It's an exchange</p> <p>23 between you and Mr. Brantley in 2014, early</p> <p>24 2014.</p>

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<p style="text-align: right;">Page 673</p> <p>1 Do you see that?</p> <p>2 A. Yes.</p> <p>3 Q. Okay. And he's passing on the</p> <p>4 charter for the advisory board of Qualitest</p> <p>5 Pharmaceuticals suspicious order monitoring</p> <p>6 program.</p> <p>7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And you told us about some of</p> <p>10 these DEA interactions, where the DEA didn't</p> <p>11 want the sales team making calls on whether</p> <p>12 orders were suspicious and customers were</p> <p>13 suspicious, right?</p> <p>14 A. Correct.</p> <p>15 Q. Okay. You implemented this</p> <p>16 particular protocol in early 2014?</p> <p>17 A. This charter, yes, when it was</p> <p>18 finalized.</p> <p>19 Q. And so what we see here is</p> <p>20 there's the SOM team, which Mr. Brantley was a</p> <p>21 part of, correct?</p> <p>22 A. Yes.</p> <p>23 Q. There was an advisory board,</p> <p>24 correct?</p>	<p style="text-align: right;">Page 675</p> <p>1 various things or recommendations?</p> <p>2 A. Yes, that's correct.</p> <p>3 </p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>
<p style="text-align: right;">Page 674</p> <p>1 A. Yes.</p> <p>2 Q. And you were a component of the</p> <p>3 advisory board?</p> <p>4 A. I believe so. I don't know where</p> <p>5 the numbers are listed, but I believe yes.</p> <p>6 Q. It's on 1148.2, "Membership."</p> <p>7 A. Yes.</p> <p>8 Q. Okay. "The advisory board shall</p> <p>9 consist of the Director of DEA compliance."</p> <p>10 That was you, right?</p> <p>11 A. Yes.</p> <p>12 Q. "Vice President Legal," who was</p> <p>13 that?</p> <p>14 A. Margaret Richardson.</p> <p>15 Q. Okay. And the Deputy Compliance</p> <p>16 Officer for generics, right?</p> <p>17 A. Yes.</p> <p>18 Q. And who was that?</p> <p>19 A. Sandra Parker.</p> <p>20 Q. Okay. And so the advisory board</p> <p>21 would consider information given to it by the</p> <p>22 SOM team, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And you guys would make calls on</p>	<p style="text-align: right;">Page 676</p> <p>1 </p> <p>2</p> <p>3</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

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<p>Page 677</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 [REDACTED]</p> <p>24 [REDACTED]</p>	<p>Page 679</p> <p>1 on this one.</p> <p>2 Do you have Exhibit 5 before you?</p> <p>3 We can work with the screen.</p> <p>4 Here you go.</p> <p>5 Exhibit 5 is that letter that you</p> <p>6 sent out to your customers in 2013.</p> <p>7 Do you recall that?</p> <p>8 A. I do.</p> <p>9 Q. And I think you called out the</p> <p>10 questionnaire in the back and a portion of the</p> <p>11 description of some of the changes you were</p> <p>12 making.</p> <p>13 Do you recall that?</p> <p>14 A. I do.</p> <p>15 Q. Okay. But what you noted in the</p> <p>16 paragraph before that, this is 594.3, it's</p> <p>17 beginning "when our products."</p> <p>18 "When our products leave the</p> <p>19 legitimate channels they have been manufactured</p> <p>20 to support, heart-wrenching consequences often</p> <p>21 occur."</p> <p>22 Do you see that?</p> <p>23 A. Yes, we've read it several times.</p> <p>24 Q. "As responsible corporate</p>
<p>Page 678</p> <p>1 [REDACTED]</p> <p>2 [REDACTED]</p> <p>3 [REDACTED]</p> <p>4 [REDACTED]</p> <p>5 [REDACTED]</p> <p>6 [REDACTED]</p> <p>7 [REDACTED]</p> <p>8 [REDACTED]</p> <p>9 [REDACTED]</p> <p>10 [REDACTED]</p> <p>11 [REDACTED]</p> <p>12 [REDACTED]</p> <p>13 [REDACTED]</p> <p>14 [REDACTED]</p> <p>15 [REDACTED]</p> <p>16 [REDACTED]</p> <p>17 [REDACTED]</p> <p>18 [REDACTED]</p> <p>19 [REDACTED]</p> <p>20 [REDACTED]</p> <p>21 [REDACTED]</p> <p>22 [REDACTED]</p> <p>23 You spent some time with defense</p> <p>24 counsel on Exhibit 5, our internal number is 594</p>	<p>Page 680</p> <p>1 citizens -- individuals, parents, friends,</p> <p>2 caregivers, relatives and acquaintances -- we</p> <p>3 need to do as much as we can to prevent drug</p> <p>4 abuse and diversion in our communities."</p> <p>5 Did I read that correctly?</p> <p>6 A. Yes.</p> <p>7 Q. "Each company and individual in</p> <p>8 the supply chain has that responsibility."</p> <p>9 Did I read that correctly?</p> <p>10 A. Yes.</p> <p>11 Q. "To put adequate controls in</p> <p>12 place to discourage and prevent the diversion of</p> <p>13 prescription products for uses other than those</p> <p>14 for which they were originally intended."</p> <p>15 Did I read that correctly?</p> <p>16 A. Yes, you did.</p> <p>17 MS. VANNI: Just note my</p> <p>18 objection, just beyond the scope. I</p> <p>19 know I used this document on direct, but</p> <p>20 I didn't refer her to that paragraph or</p> <p>21 ask her any questions about that part --</p> <p>22 MR. BUCHANAN: I understand your</p> <p>23 objection. I don't know how video will</p> <p>24 get cut at some point in time.</p>

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<p style="text-align: right;">Page 681</p> <p>1 MS. VANNI: Just preserving my 2 objection. 3 MR. BUCHANAN: Fair enough. 4 BY MR. BUCHANAN: 5 Q. Let's look at -- well, withdrawn. 6 In examination I think both with 7 Endo counsel and Anda counsel, you were asked 8 about compliance with the reg, whether acts were 9 in compliance or not with the reg regarding 10 suspicious orders, and I think you were even 11 shown the statute. 12 Do you recall that? 13 A. Yes. 14 Q. Okay. We looked yesterday, just 15 in passing, at a letter that you received from 16 DEA in 2007, you, obviously at a former company 17 at that point in time, from Mr. Rannazzisi. 18 Do you recall that? 19 A. I do. 20 Q. And you remember receiving that 21 letter? 22 A. I remember seeing the letter, 23 yes. 24 Q. Okay.</p>	<p style="text-align: right;">Page 683</p> <p>1 Q. Is this the same letter ma'am 2 that we saw in the PowerPoint yesterday that you 3 had referenced from your time at the company? 4 A. I believe it's the same letter. 5 Q. And so this is December 27, 2007, 6 several years before you joined the company, 7 correct? 8 A. Yes. 9 Q. And you acknowledge being aware 10 or at least having received it during your time 11 at a prior employer, correct? 12 A. I had seen it, yes. 13 Q. Okay. And this went to 14 manufacturers and distributors, right? 15 A. Yes. 16 Q. "The purpose of this letter is to 17 reiterate the responsibilities of controlled 18 substance manufacturers and distributors to 19 inform DEA of suspicious orders in accordance 20 with 21 CFR 1301.74(b)." 21 Do you see that? 22 A. Yes I do. 23 Q. I'd like to focus on the next 24 paragraph. It says, "In addition to, and not in</p>
<p style="text-align: right;">Page 682</p> <p>1 MR. BUCHANAN: Let's look at 2 Exhibit -- internal Exhibit Number 640. 3 (Document marked for 4 identification as Par-Norton Deposition 5 Exhibit No. 38.) 6 BY MR. BUCHANAN: 7 Q. Passing you what we're marking as 8 Exhibit 38. 9 MR. BUCHANAN: Copy for defense 10 counsel, please. 11 BY MR. BUCHANAN: 12 Q. And this is some internal 13 correspondence with Endo from before your time 14 there, attaching a letter that had been received 15 from a Mr. Rannazzisi, "Dear Registrant." 16 Do you see that? 17 A. Yes. 18 MS. VANNI: I just want to note 19 my objection to use of this document as 20 it predates her employment with the 21 company, and it's an Endo document, so 22 it doesn't even apply to her employment 23 since she wasn't an Endo employee. 24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 684</p> <p>1 lieu of, the general requirement under 21 USC 2 823, that manufacturers and distributors 3 maintain effective controls against diversion," 4 and then the sentence continues. 5 This letter is telling 6 registrants that in addition to obligation, the 7 statutory obligation to maintain effective 8 controls against diversion, there are some other 9 things we want to highlight to you about 10 suspicious order monitoring practices, fair? 11 MS. VANNI: Object to form. 12 THE WITNESS: It refers back to 13 the regulation, the CFR, yes. 14 BY MR. BUCHANAN: 15 Q. Is that a yes to my question? 16 MS. VANNI: Object to form. 17 THE WITNESS: No, I'm not sure. 18 BY MR. BUCHANAN: 19 Q. Okay. Well, you said, I think, 20 in the examination with defense counsel that you 21 took your communications from DEA as guidance, 22 correct? 23 A. I did. 24 Q. Oral communications as guidance,</p>

35 (Pages 681 to 684)

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<p style="text-align: right;">Page 685</p> <p>1 correct?</p> <p>2 A. Yes.</p> <p>3 Q. I think you were even told that</p> <p>4 DEA presentations were guidance as to</p> <p>5 compliance, correct?</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: All instructions</p> <p>8 from DEA are -- have meaning to me, and</p> <p>9 I take them seriously, yes.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Well, in fact, they told you when</p> <p>12 you sat down with them and we looked at it</p> <p>13 yesterday in the minutes of the meeting with the</p> <p>14 DEA in 2013 that all that information I just</p> <p>15 discussed, presentations, letters, statements</p> <p>16 and communications with the DEA, that was all</p> <p>17 guidance for you to incorporate as part of your</p> <p>18 compliance program, correct?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: They were</p> <p>21 suggestions for things that industry</p> <p>22 could use, yes.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. We're circle back on the minutes</p>	<p style="text-align: right;">Page 687</p> <p>1 MS. VANNI: Object to form.</p> <p>2 MR. BUCHANAN: Ma'am, move to</p> <p>3 strike the nonresponsive portion. I'm</p> <p>4 not asking whether and you were. You</p> <p>5 keep inserting that at the end. I'm</p> <p>6 supposing that maybe that's guidance.</p> <p>7 Let's stay with my questions, okay.</p> <p>8 MS. VANNI: Object to the</p> <p>9 colloquy, and I just want to note that</p> <p>10 you are at 35 minutes for Endo.</p> <p>11 MR. BUCHANAN: I'm at 35 minutes</p> <p>12 of an hour and 20 minutes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. In addition to, you understand to</p> <p>15 mean in addition to the statutory requirements,</p> <p>16 correct?</p> <p>17 MS. VANNI: Counsel, I'm sorry.</p> <p>18 Just for -- I'm sorry. I didn't mean to</p> <p>19 interrupt you. Just for clarification,</p> <p>20 is it your position that you're entitled</p> <p>21 to use the full direct, not minute for</p> <p>22 minute as used by the defendants on</p> <p>23 direct?</p> <p>24 MR. BUCHANAN: I am entitled to</p>
<p style="text-align: right;">Page 686</p> <p>1 in a moment.</p> <p>2 What this letter is -- and so</p> <p>3 this would be guidance to you, this letter,</p> <p>4 correct?</p> <p>5 A. Yes.</p> <p>6 Q. As to what the DEA was expecting</p> <p>7 of you as a registrant, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Okay. And so it says "In</p> <p>10 addition to, and not in lieu of."</p> <p>11 Do you have an understanding what</p> <p>12 that means?</p> <p>13 A. I do.</p> <p>14 Q. And what does it mean?</p> <p>15 A. It means instead of versus, yeah,</p> <p>16 this end instead -- you can't substitute one for</p> <p>17 the other.</p> <p>18 Q. That's right. I mean, you have</p> <p>19 an obligation, obviously, to do suspicious order</p> <p>20 monitoring, and you have an obligation to</p> <p>21 maintain effective controls against diversion,</p> <p>22 correct?</p> <p>23 A. Absolutely and we were.</p> <p>24 MS. KOSKI: Object.</p>	<p style="text-align: right;">Page 688</p> <p>1 use minute for minute of the redirect</p> <p>2 examination conducted by you or your</p> <p>3 direct examination used by you.</p> <p>4 MS. VANNI: That would be 35</p> <p>5 minutes for Endo.</p> <p>6 MR. BUCHANAN: No, I mean "you"</p> <p>7 as defendants.</p> <p>8 MS. VANNI: Okay. We object to</p> <p>9 that position, but -- so just note our</p> <p>10 objection.</p> <p>11 MR. BUCHANAN: That hasn't been</p> <p>12 my understanding, but I've been doing</p> <p>13 issues that concern Anda as part of</p> <p>14 this. I'm not sequencing specifically</p> <p>15 between Anda and Endo.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. This Rannazzisi letter that was</p> <p>18 received in 2007 by registrants, and we saw it</p> <p>19 copied in your PowerPoint, reflects that the</p> <p>20 requirements under the CFR are in addition to</p> <p>21 and not in lieu of those in the statute,</p> <p>22 correct?</p> <p>23 A. That's what it says.</p> <p>24 Q. Thank you.</p>

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<p style="text-align: right;">Page 689</p> <p>1 And let's look at that with</p> <p>2 regard to -- so a manufacturer or a distributor</p> <p>3 has an obligation to maintain effective controls</p> <p>4 against diversion, right?</p> <p>5 A. Yes, as identified in the</p> <p>6 regulation.</p> <p>7 Q. Statutory -- I'm sorry. As</p> <p>8 identified in the statute?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. Has an obligation to</p> <p>11 maintain effective controls against diversion,</p> <p>12 that's the statutory obligation, correct?</p> <p>13 A. Yes.</p> <p>14 Q. And Mr. Rannazzisi is saying you</p> <p>15 have a separate obligation with regard to the</p> <p>16 CFR, the regulation, with regard to suspicious</p> <p>17 order monitoring and reporting, correct?</p> <p>18 MS. KOSKI: Object to form.</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Okay. And so in this letter -- I</p> <p>23 mean, you'd agree this is important guidance</p> <p>24 from DEA, correct?</p>	<p style="text-align: right;">Page 691</p> <p>1 A. Yes.</p> <p>2 Q. Okay. "The determination of</p> <p>3 whether an order is suspicious depends not only</p> <p>4 on the ordering patterns of the particular</p> <p>5 customer, but also on the patterns of the</p> <p>6 registrant's customer base and the patterns</p> <p>7 throughout the relevant segment of the regulated</p> <p>8 industry."</p> <p>9 Did I read that correctly?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. So what this is saying is,</p> <p>12 one, your system has got to look at patterns,</p> <p>13 right?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Isn't that what he wrote?</p> <p>17 A. It says if you're looking at</p> <p>18 patterns, the size of the order alone is</p> <p>19 different than -- basically that they're not --</p> <p>20 you can't base a decision on one versus the</p> <p>21 other.</p> <p>22 Q. Let's look at what's written by</p> <p>23 the DEA to registrants.</p> <p>24 "The determination of whether an</p>
<p style="text-align: right;">Page 690</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: It's guidance.</p> <p>3 It's not anything that wasn't well known</p> <p>4 at the time.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. Well, let's see what was,</p> <p>7 again, then well known at the time before you</p> <p>8 got this letter.</p> <p>9 "The regulation specifically</p> <p>10 states that suspicious orders include orders of</p> <p>11 unusual size, orders deviating from a normal</p> <p>12 pattern and orders of an unusual frequency."</p> <p>13 Would you agree that's what he</p> <p>14 wrote?</p> <p>15 A. That's what it says, yes.</p> <p>16 Q. Can you go to third paragraph,</p> <p>17 please. It continue, "The size of order alone,</p> <p>18 whether or not it deviates from a normal</p> <p>19 pattern, is enough to trigger the registrant's</p> <p>20 responsibility to report the order as</p> <p>21 suspicious."</p> <p>22 Do you see that? It's the --</p> <p>23 sorry, fourth paragraph.</p> <p>24 Do you see that, ma'am?</p>	<p style="text-align: right;">Page 692</p> <p>1 order is suspicious depends not only on the</p> <p>2 ordering patterns of the particular customer,</p> <p>3 but also on the patterns of the registrant's</p> <p>4 customer base and the patterns throughout the</p> <p>5 relevant segment of the regulated industry."</p> <p>6 Did I read that correctly?</p> <p>7 A. You read it correctly.</p> <p>8 Q. Okay. And as of the time you got</p> <p>9 to Qualitest, was the Qualitest suspicious order</p> <p>10 monitoring system looking at class of trade as</p> <p>11 separate thresholds?</p> <p>12 A. Again, I can't comment on what</p> <p>13 the system was --</p> <p>14 MS. VANNI: Objection.</p> <p>15 THE WITNESS: -- before I got</p> <p>16 there.</p> <p>17 MS. VANNI: Beyond the scope.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. At the time you got there. At</p> <p>20 the time you got there, ma'am, was it looking at</p> <p>21 relevant classes of trade?</p> <p>22 MS. VANNI: Objection, asked and</p> <p>23 answered.</p> <p>24 THE WITNESS: I don't know what</p>

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<p style="text-align: right;">Page 693</p> <p>1 OMS was doing.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. Okay. The next page it says,</p> <p>4 "Registrants that rely on rigid formulas to</p> <p>5 define whether an order is suspicious may be</p> <p>6 failing to detect suspicious orders."</p> <p>7 Did I read that correctly?</p> <p>8 A. You did.</p> <p>9 Q. "For example, a system that</p> <p>10 identifies orders as suspicious only if the</p> <p>11 total amount of a controlled substance order</p> <p>12 during one month exceeds the amount ordered the</p> <p>13 previous month by a certain percentage or more</p> <p>14 is" -- what did Mr. Rannazzisi say?</p> <p>15 A. "Is insufficient."</p> <p>16 Q. "Is insufficient." So you had</p> <p>17 that knowledge as of 2007, right?</p> <p>18 MS. VANNI: Object to form.</p> <p>19 THE WITNESS: In other words,</p> <p>20 don't rely on pattern.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. It says something that is looking</p> <p>23 at whether or not it just exceeds a</p> <p>24 predetermined percentage from a prior month is</p>	<p style="text-align: right;">Page 695</p> <p>1 Q. Nonetheless, you had this</p> <p>2 guidance from the DEA as of the end of 2007, and</p> <p>3 I think you even said this was known before,</p> <p>4 right?</p> <p>5 MS. KOSKI: Object to form.</p> <p>6 MS. VANNI: Object to form.</p> <p>7 THE WITNESS: The letter was out</p> <p>8 there.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. And, "Also, this system would not</p> <p>11 identify orders as suspicious if the order were</p> <p>12 solely for one highly abused controlled</p> <p>13 substance if the orders never grew</p> <p>14 substantially."</p> <p>15 Did I read that correctly?</p> <p>16 A. You did.</p> <p>17 Q. "Nevertheless, ordering one</p> <p>18 highly abused controlled substance and little or</p> <p>19 nothing else deviates from the normal pattern of</p> <p>20 what pharmacies generally order."</p> <p>21 Did I read that correctly?</p> <p>22 A. You did.</p> <p>23 Q. This is that product mix issue</p> <p>24 that the DEA discussed with you later in time,</p>
<p style="text-align: right;">Page 694</p> <p>1 insufficient, correct?</p> <p>2 A. Which is the frequency of the</p> <p>3 order. That's what it says, yes.</p> <p>4 Q. "A system that identifies orders</p> <p>5 as suspicious only if the total amount of a</p> <p>6 controlled substance ordered during one month</p> <p>7 exceeds the amount ordered the previous month by</p> <p>8 a certain percentage or more is insufficient."</p> <p>9 Those are the words, right?</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: That's what it</p> <p>12 says, yes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. Okay. "This system fails to</p> <p>15 identify orders placed by a pharmacy if the</p> <p>16 pharmacy placed unusually large orders from the</p> <p>17 beginning of its relationship with the</p> <p>18 distributor."</p> <p>19 Do you agree with that, ma'am?</p> <p>20 A. That's what it says.</p> <p>21 Q. Okay. And you agree?</p> <p>22 MS. LEIBELL: Object to form.</p> <p>23 THE WITNESS: No.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 696</p> <p>1 correct?</p> <p>2 MS. KOSKI: Object to form.</p> <p>3 MS. VANNI: Object to form.</p> <p>4 THE WITNESS: I can't -- can't</p> <p>5 connect the two.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. Okay. Well, let's talk about it.</p> <p>8 "Ordering one highly abused controlled substance</p> <p>9 and little or nothing else deviates from the</p> <p>10 normal pattern of what pharmacies generally</p> <p>11 order."</p> <p>12 Did I read that correctly?</p> <p>13 A. He's making a statement about</p> <p>14 pharmacies. I mean, I think you're reading more</p> <p>15 into what he's saying than is there but...</p> <p>16 Q. You told us, ma'am, that these</p> <p>17 are important guidances, and this is what you</p> <p>18 governed your actions by, right?</p> <p>19 MS. KOSKI: Object to form.</p> <p>20 MS. VANNI: Object to form.</p> <p>21 THE WITNESS: They are things</p> <p>22 that I take into consideration, yes.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Well, if the DEA is telling you</p>

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<p style="text-align: right;">Page 697</p> <p>1 this is what you need to do to comply, then this</p> <p>2 is what you need to do to comply, right?</p> <p>3 MS. KOSKI: Object to form.</p> <p>4 THE WITNESS: And we did.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. And so Qualitest was</p> <p>7 considering the relative percentages of</p> <p>8 controlled substances versus noncontrolled</p> <p>9 substances of its customers prior to 2013,</p> <p>10 ma'am?</p> <p>11 A. I don't know, again, what OMS was</p> <p>12 doing.</p> <p>13 Q. Okay. You're not aware that</p> <p>14 Qualitest was doing that, correct?</p> <p>15 MS. VANNI: Object to form.</p> <p>16 THE WITNESS: I don't know. I</p> <p>17 can't comment.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. Okay. You have no information to</p> <p>20 share with us as to whether Qualitest was doing</p> <p>21 that, correct?</p> <p>22 MS. VANNI: Object to form.</p> <p>23 THE WITNESS: Do not, no.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 699</p> <p>1 MR. BUCHANAN: Okay.</p> <p>2 THE WITNESS: Manufacturers and</p> <p>3 distributors.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Fair enough, to manufacturers and</p> <p>6 distributors. Okay.</p> <p>7 All right. So every year that</p> <p>8 Qualitest or any of the entities you were with</p> <p>9 filed a application with the DEA to get</p> <p>10 permission to manufacture, to distribute, to</p> <p>11 sell controlled substances, you were agreeing to</p> <p>12 play within that framework, right?</p> <p>13 MS. KOSKI: Object to form.</p> <p>14 MS. VANNI: Objection.</p> <p>15 THE WITNESS: We were agreeing to</p> <p>16 abide by the DEA regulations.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. You were agreeing to maintain</p> <p>19 effective controls against diversion, one,</p> <p>20 correct?</p> <p>21 MS. VANNI: Objection.</p> <p>22 THE WITNESS: Which we did, yes.</p> <p>23 All of the recordkeeping and</p> <p>24 accountability and storage requirements</p>
<p style="text-align: right;">Page 698</p> <p>1 Q. Okay. Paragraph beginning</p> <p>2 "lastly."</p> <p>3 Lastly, registrants that</p> <p>4 routinely report suspicious orders, yet fill</p> <p>5 these orders without first determining that the</p> <p>6 order is not being diverted into other than</p> <p>7 legitimate medical scientific and industrial</p> <p>8 channels may be failing to maintain effective</p> <p>9 controls against diversion.</p> <p>10 Did I read that correctly?</p> <p>11 A. Yes, you did.</p> <p>12 Q. And you have that knowledge and</p> <p>13 understanding as of 2007 at the latest, ma'am?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 THE WITNESS: That's what he's</p> <p>16 saying in 2007, yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And he is the DEA at this point?</p> <p>19 A. Yes.</p> <p>20 Q. Okay. And this is a DEA</p> <p>21 communication to all registrants, correct?</p> <p>22 MS. KOSKI: Object to form.</p> <p>23 THE WITNESS: It is a</p> <p>24 communication to some registrants, yes.</p>	<p style="text-align: right;">Page 700</p> <p>1 were met.</p> <p>2 MR. BUCHANAN: Move to strike.</p> <p>3 You did it again. Let's stay with my</p> <p>4 question.</p> <p>5 MS. KOSKI: Objection.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. When you apply for a</p> <p>8 registration, you are agreeing to maintain</p> <p>9 effective controls against diversion, correct?</p> <p>10 A. Yes, and we did.</p> <p>11 MR. BUCHANAN: Move to strike.</p> <p>12 BY MR. BUCHANAN:</p> <p>13 Q. Are you having a hard time just</p> <p>14 staying with my focus?</p> <p>15 MS. VANNI: Object to colloquy.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Are you having a hard time with</p> <p>18 that?</p> <p>19 A. No.</p> <p>20 Q. Okay. When you file an</p> <p>21 application with the DEA to be a registrant as</p> <p>22 either a manufacturer or a distributor, you are</p> <p>23 agreeing that you will maintain effective</p> <p>24 controls to prevent diversion, yes or no?</p>

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<p style="text-align: right;">Page 701</p> <p>1 A. Yes.</p> <p>2 MS. VANNI: Objection, asked and</p> <p>3 answered.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. When you make an application to</p> <p>6 be a registrant, you are agreeing that you will</p> <p>7 comply with the regulations concerning</p> <p>8 suspicious order monitoring, yes or no?</p> <p>9 MS. KOSKI: Objection to form.</p> <p>10 MS. VANNI: Objection, asked and</p> <p>11 answered.</p> <p>12 THE WITNESS: Yes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. You agree not just the first</p> <p>15 time, you agree every time you do that; yes or</p> <p>16 no?</p> <p>17 MS. VANNI: Objection.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. And so if you're agreeing to do</p> <p>21 that, it's not unreasonable for the DEA to</p> <p>22 believe that you're doing that, correct?</p> <p>23 MS. VANNI: Objection.</p> <p>24 THE WITNESS: Yes, and to</p>	<p style="text-align: right;">Page 703</p> <p>1 order monitoring program to detect suspicious</p> <p>2 orders, correct?</p> <p>3 MS. KOSKI: Objection.</p> <p>4 MS. VANNI: Objection, asked and</p> <p>5 answered.</p> <p>6 THE WITNESS: As done, yes.</p> <p>7 MR. BUCHANAN: Move to strike.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. And you also had the obligation,</p> <p>10 and you agreed every time you renewed, that you</p> <p>11 were maintaining a suspicious order monitoring</p> <p>12 program compliant with the DEA guidance,</p> <p>13 correct?</p> <p>14 MS. KOSKI: Object to form.</p> <p>15 MS. VANNI: Objection.</p> <p>16 THE WITNESS: Yes.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. And if you weren't doing so, and</p> <p>19 if you weren't doing so, that would be a very</p> <p>20 serious breach of not only the promise you made</p> <p>21 as part of your registration but also the public</p> <p>22 trust, yes or no?</p> <p>23 MS. KOSKI: Objection.</p> <p>24 MS. VANNI: Objection.</p>
<p style="text-align: right;">Page 702</p> <p>1 inspect, to confirm.</p> <p>2 BY MR. BUCHANAN:</p> <p>3 Q. You saw the interaction with the</p> <p>4 DEA yesterday, where you were told that you had</p> <p>5 the public trust in your hands.</p> <p>6 Do you recall hearing that from</p> <p>7 the DEA in 2013?</p> <p>8 A. Yes.</p> <p>9 MS. VANNI: Objection.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. You had that understanding as a</p> <p>12 DEA compliance officer, correct?</p> <p>13 A. Yes.</p> <p>14 Q. That not just -- the obligation</p> <p>15 wasn't just to make the pills and put them out</p> <p>16 there, but to maintain effective controls</p> <p>17 against diversion when you were doing that.</p> <p>18 You understood that, correct?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Yes.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. And to maintain appropriate --</p> <p>23 withdrawn.</p> <p>24 And to maintain a suspicious</p>	<p style="text-align: right;">Page 704</p> <p>1 THE WITNESS: That would be not</p> <p>2 complying with the regulation.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. And a breach of the public trust;</p> <p>5 do you agree with that?</p> <p>6 MS. VANNI: Objection.</p> <p>7 THE WITNESS: It's not up to me</p> <p>8 to define what's a breach of the public</p> <p>9 trust.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. You understand that you can't</p> <p>12 do -- you being Qualitest, a manufacturer and</p> <p>13 distributor of controlled substances during the</p> <p>14 time you were there or with any of the</p> <p>15 manufacturers and distributors that you worked</p> <p>16 with, you can't do what you do without the</p> <p>17 permission slip that's obtained following the</p> <p>18 promise you make to do those things, right?</p> <p>19 MS. VANNI: Object to form.</p> <p>20 THE WITNESS: Following the grant</p> <p>21 of the license by DEA.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. And the promise that the</p> <p>24 registrant will maintain effective controls</p>

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<p style="text-align: right;">Page 705</p> <p>1 against diversion and a suspicious order</p> <p>2 monitoring program to detect suspicious orders;</p> <p>3 you would agree, correct?</p> <p>4 MS. VANNI: Object to form.</p> <p>5 THE WITNESS: We have to comply</p> <p>6 with the regulations.</p> <p>7 MS. VANNI: My real time is down.</p> <p>8 Could we go off the record.</p> <p>9 THE VIDEOGRAPHER: The time is</p> <p>10 now 11:15 a.m. We are off the record.</p> <p>11 (Pause.)</p> <p>12 THE VIDEOGRAPHER: The time is</p> <p>13 11:18. We are back on the record.</p> <p>14 BY MR. BUCHANAN:</p> <p>15 Q. Ma'am, you have 640.1 before you.</p> <p>16 Let me just see the exhibit number, though.</p> <p>17 Internal Number 640.1, 38 for the deposition.</p> <p>18 MR. BUCHANAN: Could we pull up</p> <p>19 that one.</p> <p>20 MS. VANNI: Could I have a copy?</p> <p>21 MR. BUCHANAN: You have it. It's</p> <p>22 already been marked.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. So on Exhibit 38 on the first</p>	<p style="text-align: right;">Page 707</p> <p>1 issues?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: I don't know.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. What he notes in this e-mail, can</p> <p>6 we have it on the screen here, "The HDMA is</p> <p>7 objecting to the attached DEA notice and is</p> <p>8 presenting to the Pain Care Forum tomorrow."</p> <p>9 Did I read that correctly?</p> <p>10 A. You did.</p> <p>11 Q. The attached notice is the notice</p> <p>12 we were looking at from Mr. Rannazzisi and the</p> <p>13 DEA in 2007, correct?</p> <p>14 A. Yes.</p> <p>15 Q. Okay. Did you know that that was</p> <p>16 one of the things HDMA was doing with regard to</p> <p>17 the guidances industry was receiving concerning</p> <p>18 suspicious order monitoring and anti-diversion</p> <p>19 efforts?</p> <p>20 A. No, I wasn't --</p> <p>21 MS. VANNI: Object to form.</p> <p>22 MR. LEEDER: Object to form.</p> <p>23 THE WITNESS: -- involved and</p> <p>24 didn't have knowledge of that.</p>
<p style="text-align: right;">Page 706</p> <p>1 page, ma'am, I understand you were not at</p> <p>2 Qualitest at this point in time.</p> <p>3 Did you have familiarity with the</p> <p>4 HDMA?</p> <p>5 A. Not at this time, no.</p> <p>6 Q. When did you get involved with</p> <p>7 HDMA?</p> <p>8 A. When I worked for HD Smith.</p> <p>9 Q. Okay. So at a late -- roughly</p> <p>10 ten years later, I guess?</p> <p>11 A. Yes.</p> <p>12 Q. Or eight years later, whatever it</p> <p>13 is.</p> <p>14 This e-mail notes that the HDMA,</p> <p>15 that's from Brian Munroe to a distribution list</p> <p>16 of people that probably included some and didn't</p> <p>17 include others from your time at Endo and</p> <p>18 Qualitest, he was the vice president of</p> <p>19 government affairs.</p> <p>20 Did you have any opportunity to</p> <p>21 deal with him during your time at Qualitest?</p> <p>22 A. I did.</p> <p>23 Q. Okay. I understood he had</p> <p>24 relations and interactions with HDMA on various</p>	<p style="text-align: right;">Page 708</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. Did you know industry was</p> <p>3 objecting --</p> <p>4 A. No.</p> <p>5 MS. VANNI: Object to form.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. -- to the DEA's requirements?</p> <p>8 A. No, I did not.</p> <p>9 Q. Okay. "This is worth looking at</p> <p>10 as it represents the continuing 'creep' of the</p> <p>11 DEA into activities that contribute to the</p> <p>12 overall chilling effect of prescribing pain</p> <p>13 medications."</p> <p>14 Did I read that correctly?</p> <p>15 A. You did.</p> <p>16 Q. Okay. And were you involved at</p> <p>17 all with HDMA in trying to combat DEA</p> <p>18 regulations?</p> <p>19 A. No.</p> <p>20 MS. VANNI: Object to form.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Okay. Or guidances?</p> <p>23 A. No.</p> <p>24 Q. Okay. Were you a part of Watson</p>

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<p style="text-align: right;">Page 709</p> <p>1 or Anda's efforts with the HDMA at this point in 2 time? 3 A. No. 4 MS. KOSKI: Object to form. 5 MS. LEIBELL: Object to form. 6 BY MR. BUCHANAN: 7 Q. Okay. Did you tell your peers at 8 Watson or Anda at that point in time we've got 9 to resist this obligation for our companies? 10 A. No. 11 MS. LEIBELL: Object to form. 12 MS. KOSKI: Object to form. 13 BY MR. BUCHANAN: 14 Q. Did you know that others were 15 doing that? 16 A. I did not. 17 Q. Okay. You talked about other 18 industry organizations in your direct 19 examination with Endo counsel. I think you 20 mentioned the Anti-Diversion Industry Working 21 Group, a red flags video. 22 Do you recall that? 23 A. I do. 24 Q. Pass you what we're marking as</p>	<p style="text-align: right;">Page 711</p> <p>1 video issues, right? 2 A. Yes. 3 Q. Were you a part of the review 4 process for the red flag video, ma'am? 5 A. I was. 6 Q. I see Qualitest was also 7 involved? 8 A. Yes, when I worked for Qualitest. 9 Q. Okay. And that was -- 10 A. That's me. 11 Q. You're actually referenced on the 12 press release announcing the red flag video? 13 A. Yes. 14 Q. And so you endorsed its content? 15 MS. VANNI: Object to form. 16 THE WITNESS: I did. 17 BY MR. BUCHANAN: 18 Q. You reviewed its contents? 19 A. Yes. 20 Q. Okay. And then you sent it 21 around to others in the company as a -- to show 22 them, frankly, what the anti-diversion working 23 group had done? 24 A. Yes.</p>
<p style="text-align: right;">Page 710</p> <p>1 Exhibit -- it's internal number 1080 for the 2 deposition -- 39. 3 (Document marked for 4 identification as Par-Norton Deposition 5 Exhibit No. 39.) 6 BY MR. BUCHANAN: 7 Q. Passing you Exhibit 39 to your 8 deposition. There you go. This is a press 9 release that issued around the time the red flag 10 video was released; is that right? 11 A. Yes. 12 Q. And we looked at a document 13 yesterday concerning the anti-diversion working 14 group, where there was a reference to maybe we 15 should do something like this. 16 Do you recall that? 17 A. I'm sorry? 18 Q. I said we looked at a -- I think 19 it was a meeting of -- your minutes having 20 attended an anti-diversion working group meeting 21 where, among other things, one thing that was 22 discussed was the development of this video? 23 A. Yes. 24 Q. Okay. So that occurs and the</p>	<p style="text-align: right;">Page 712</p> <p>1 MR. BUCHANAN: Do we have a copy 2 of the video I can give to counsel? I 3 need a copy of the video, though, just 4 for the record. 5 (Thumb drive marked for 6 identification as Par-Norton Deposition 7 Exhibit No. 40.) 8 MR. BUCHANAN: All right. I'm 9 just marking as Exhibit 40 a thumb drive 10 which has a copy of the video. I'd like 11 you to watch with me now as we pull it 12 up on the screen. 13 Can you pull the red flag video 14 up on the screen. Can you go to the 15 start of it first, and let's just get it 16 rolling for a moment. Can you 17 transcribe what's played. 18 (Video played as follows: 19 "I'm Carmen Collazo, executive 20 director for the examination" -- 21 MR. BUCHANAN: Let's pause. We 22 don't have enough volume. 23 THE VIDEOGRAPHER: The time is 24 11:24. Off the record.</p>

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<p style="text-align: right;">Page 713</p> <p>1 (Brief recess.)</p> <p>2 THE VIDEOGRAPHER: The time is</p> <p>3 11:30. We are back on the record.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Ma'am, you were telling us</p> <p>6 yesterday about your involvement with the</p> <p>7 anti-diversion working group. You also just</p> <p>8 discussed with us your involvement with the</p> <p>9 preparation of the red flag video both</p> <p>10 individually and on behalf of Qualitest.</p> <p>11 Do you recall that testimony?</p> <p>12 A. I do.</p> <p>13 Q. Okay. I'd like to just put it on</p> <p>14 the screen and just confirm that we're talking</p> <p>15 about the same thing, okay?</p> <p>16 A. Yes.</p> <p>17 MR. BUCHANAN: Can you queue it</p> <p>18 up please and pause for a second.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. This is NABP red flag video. You</p> <p>21 saw the title flash on the screen, ma'am?</p> <p>22 A. I did.</p> <p>23 Q. Okay. And you recognize this</p> <p>24 individual?</p>	<p style="text-align: right;">Page 715</p> <p>1 show actually faces of individuals struggling</p> <p>2 with opioids, right?</p> <p>3 MS. BANNI: Object to form.</p> <p>4 THE WITNESS: Yes.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. One of the points being, these</p> <p>7 are everyday people who are addicted?</p> <p>8 A. That's the point --</p> <p>9 MS. BANNI: Object to form.</p> <p>10 THE WITNESS: -- yes.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. The point of showing faces of all</p> <p>13 ilks is to say this is a drug abuse issue that</p> <p>14 is different than drug abuse that people might</p> <p>15 ordinarily be thinking of, right?</p> <p>16 MS. KOSKI: Object to form.</p> <p>17 MS. BANNI: Object to form.</p> <p>18 THE WITNESS: I'm not sure, but</p> <p>19 it's meant to show that there are</p> <p>20 different types of people who face</p> <p>21 addiction.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. And the jury will have the full</p> <p>24 video to review and see what was trying to be</p>
<p style="text-align: right;">Page 714</p> <p>1 A. Yes.</p> <p>2 Q. And who is he?</p> <p>3 A. Carmen Collazo, the head of the</p> <p>4 National Association of Boards of Pharmacy.</p> <p>5 Q. Could we go to -- we don't have</p> <p>6 the time to listen to all 12 minutes. We're</p> <p>7 going to hit a few places. But fair to say that</p> <p>8 what's happening here is the company is</p> <p>9 presenting -- I'm sorry -- the anti-diversion</p> <p>10 working group together with the ABMP is</p> <p>11 presenting situations and scenarios that may</p> <p>12 occur in pharmacies to sensitize pharmacists and</p> <p>13 pharmacies to maybe things they can do to help</p> <p>14 prevent diversion.</p> <p>15 A. Yes.</p> <p>16 Q. Would that be fair?</p> <p>17 MS. VANNI: Object to form.</p> <p>18 MR. BUCHANAN: Let's go to 2:21.</p> <p>19 Okay. That's actually helpful. That</p> <p>20 will refresh the witness' recollection</p> <p>21 more broadly.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. And one of the things the video</p> <p>24 did and we see it on the screen right now is</p>	<p style="text-align: right;">Page 716</p> <p>1 conveyed --</p> <p>2 A. Yes.</p> <p>3 Q. -- by the anti-diversion working</p> <p>4 group, together in collaboration with the ABMP,</p> <p>5 but I would like to focus on some specific</p> <p>6 language with you now. Could we go to 2:21. Is</p> <p>7 it ready to play? All right. Now we'll play</p> <p>8 some clips and I'll ask you some questions.</p> <p>9 (Video played as follows:</p> <p>10 "Opioid abuse is a nationwide</p> <p>11 epidemic. Every 19 minutes someone dies</p> <p>12 from an unintentional drug overdose and</p> <p>13 when it comes to overdose deaths caused</p> <p>14 by prescription drugs, nearly three out</p> <p>15 of four are caused by painkillers. The</p> <p>16 number of deaths involving opioids now</p> <p>17 outnumbers those from cocaine and heroin</p> <p>18 combined. Regulations" --)</p> <p>19 MR. BUCHANAN: You can press</p> <p>20 pause.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. You recall that portion of the</p> <p>23 video, ma'am?</p> <p>24 A. I do.</p>

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<p>1 Q. You were involved in its 2 preparation? 3 A. I was involved in -- I didn't -- 4 I didn't draft the wording for it, but I was -- 5 I reviewed it before, yes. 6 Q. I think you told us a few minutes 7 ago you reviewed and endorsed it, right? 8 A. Yes. 9 Q. Okay. Content was accurate when 10 written? 11 MS. BANNI: Object to form. 12 THE WITNESS: I don't know if you 13 say accurate. It was -- it sounded -- 14 it sounded right when I reviewed it. 15 BY MR. BUCHANAN: 16 Q. Right, I mean, you were certainly 17 trying to make sure that it was accurate when 18 you were putting it out and distributing it on a 19 website for pharmacies around the country, 20 right? 21 MS. BANNI: Object to form. 22 THE WITNESS: We did not put it 23 out and distribute it on a website. 24 That was done by NABP.</p>	<p>1 another doctor, right? 2 MS. BANNI: Object to form. 3 THE WITNESS: These were things 4 that we had been told by DEA were 5 issues, yes. 6 BY MR. BUCHANAN: 7 Q. And we see people on the screen, 8 and these are people that, could we agree, are 9 everyday folks? 10 MS. BANNI: Object to form. 11 MS. KOSKI: Object to form. 12 THE WITNESS: I guess, yeah. 13 MR. BUCHANAN: Okay. Let's play 14 from 4:56. 15 (Video played as follows: 16 "For every unintentional overdose 17 death from opioids in 2010, there were 18 733 nonmedical users. Emergency room 19 visits resulting from pharmaceutical 20 abuse with no other type of drug or 21 alcohol involved almost doubled between 22 2004 and 2010.") 23 MR. BUCHANAN: Press pause, 24 please.</p>
Page 718	Page 720
<p>1 BY MR. BUCHANAN: 2 Q. Well, the anti-diversion working 3 group issued a press release, right? 4 A. I believe Mallinckrodt issued a 5 press release and noted everybody on there, yes. 6 Q. Right. And you endorsed its 7 content when it was released, correct? 8 MS. BANNI: Object to form. 9 THE WITNESS: Yes. 10 BY MR. BUCHANAN: 11 Q. Even sent it around to your peers 12 in the firms to show it to them, right? 13 A. Right. It was something that I 14 was proud that we had -- we had done. 15 Q. Okay. Let's go to 4:56, and 16 we're kind of scrubbing through the images. 17 Does that refresh your recollection in terms of 18 its content? 19 A. Yes. 20 Q. People walking up to a counter, 21 red flags, cash customers, people walking in in 22 groups? 23 A. Mm-hmm. 24 Q. People going from one doctor to</p>	<p>1 BY MR. BUCHANAN: 2 Q. Big problem, can we agree? 3 MS. BANNI: Object to form. 4 THE WITNESS: Big problem, there 5 is an addiction problem in the United 6 States, yes. 7 BY MR. BUCHANAN: 8 Q. For every opioid death in 2010, 9 there were 733 nonmedical users of those drugs, 10 right? 11 A. That's what this -- the data 12 showed. I'm not sure where the data came from, 13 I don't recall, but it was probably from a 14 regulatory agency. 15 Q. Data you endorsed as accurate at 16 that point in time personally, correct? 17 MS. BANNI: Object to form. 18 THE WITNESS: Yes. 19 BY MR. BUCHANAN: 20 Q. Data you endorsed as accurate on 21 behalf of the anti-diversion working group, 22 correct? 23 MS. BANNI: Object to form. 24 THE WITNESS: Yes.</p>

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<p style="text-align: right;">Page 721</p> <p>1 BY MR. BUCHANAN:</p> <p>2 Q. We've seen stats on opioid</p> <p>3 deaths. You're familiar there's stats out</p> <p>4 there, right?</p> <p>5 A. Yes.</p> <p>6 Q. As of this point in time, you had</p> <p>7 the knowledge that for every death there were</p> <p>8 733 people who were using opioids for nonmedical</p> <p>9 use, right?</p> <p>10 MS. BANNI: Objection, beyond the</p> <p>11 scope.</p> <p>12 THE WITNESS: It's all stats that</p> <p>13 are out there. We took the stats as</p> <p>14 they were. I don't know what the</p> <p>15 details were before into them and how</p> <p>16 they were obtained, but we assumed they</p> <p>17 were accurate based on the source.</p> <p>18 BY MR. BUCHANAN:</p> <p>19 Q. You certainly were trying to</p> <p>20 convey accurate information, correct?</p> <p>21 A. Yes, we were.</p> <p>22 Q. And, to the best of your</p> <p>23 knowledge, ma'am, you did so, correct?</p> <p>24 A. Yes.</p>	<p style="text-align: right;">Page 723</p> <p>1 MS. VANNI: Object to form.</p> <p>2 THE WITNESS: It's one of the</p> <p>3 things that's outlined on DEA's website</p> <p>4 and why they do their national take back</p> <p>5 days now, yes.</p> <p>6 BY MR. BUCHANAN:</p> <p>7 Q. And the manufacturers who you</p> <p>8 worked with in the anti-diversion working group</p> <p>9 endorse that as a true statement of the state of</p> <p>10 affairs as of 2014 when this video was prepared,</p> <p>11 correct?</p> <p>12 MS. VANNI: Objection.</p> <p>13 THE WITNESS: Yes, there's always</p> <p>14 independent thought and people who will</p> <p>15 abuse and take things in ways they</p> <p>16 shouldn't.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. America's drug problem isn't on</p> <p>19 the streets, it's in our medicine cabinets,</p> <p>20 right?</p> <p>21 A. In that particular case, yes,</p> <p>22 when we were directing to pharmacies, yes, that</p> <p>23 is the case.</p> <p>24 MR. BUCHANAN: Let's go to nine</p>
<p style="text-align: right;">Page 722</p> <p>1 Q. Okay. Let's go forward now to</p> <p>2 8:25. And we see kind of interspersed with</p> <p>3 facts these scenarios with individuals</p> <p>4 approaching a pharmacy counter, fair?</p> <p>5 A. Yes.</p> <p>6 Q. Okay.</p> <p>7 MR. BUCHANAN: Could you play</p> <p>8 8:25.</p> <p>9 (Video played as follows:</p> <p>10 "America's biggest drug problem</p> <p>11 isn't on the streets, it's in our</p> <p>12 medicine cabinets. Seventy percent of</p> <p>13 Americans are taking at least one</p> <p>14 prescription drug and more than 50% are</p> <p>15 on at least two. Among young people who</p> <p>16 abuse prescription medications, 70% get</p> <p>17 them from family or friends.")</p> <p>18 MR. BUCHANAN: Let's pause.</p> <p>19 BY MR. BUCHANAN:</p> <p>20 Q. America's drug problem isn't on</p> <p>21 the streets, it's in our medicine cabinet.</p> <p>22 Did you hear that?</p> <p>23 A. I did.</p> <p>24 Q. True statement when made, right?</p>	<p style="text-align: right;">Page 724</p> <p>1 minutes and three seconds and play that</p> <p>2 portion.</p> <p>3 (Video played as follows:</p> <p>4 "More Americans abuse</p> <p>5 prescription drugs than the number of</p> <p>6 cocaine, hallucinogen, methamphetamine</p> <p>7 and heroin abusers combined. The</p> <p>8 pharmacy" --)</p> <p>9 MR. BUCHANAN: Let's pause there.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. More Americans abuse prescription</p> <p>12 drugs than cocaine, hallucinogens,</p> <p>13 methamphetamine and heroin abusers combined.</p> <p>14 Did you hear that, ma'am?</p> <p>15 A. I did.</p> <p>16 Q. To your knowledge in 2014, that</p> <p>17 was a true statement you were making through the</p> <p>18 anti-diversion working group for this video,</p> <p>19 correct?</p> <p>20 A. Those were statements that have</p> <p>21 would come from DEA or CDC or a regulator, so I</p> <p>22 would assume, yes.</p> <p>23 Q. You certainly wouldn't endorse</p> <p>24 them as appropriate or true if they weren't</p>

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<p>1 true, right?</p> <p>2 MS. VANNI: Object to form.</p> <p>3 THE WITNESS: Yes.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. To the best of your knowledge,</p> <p>6 ma'am, as a person who was on this committee to</p> <p>7 review and endorse this video, those were true,</p> <p>8 right?</p> <p>9 A. Those --</p> <p>10 MS. VANNI: Object to form.</p> <p>11 THE WITNESS: Those were publicly</p> <p>12 available.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. To the best of your knowledge,</p> <p>15 they were true?</p> <p>16 A. I wasn't in a position to make a</p> <p>17 determination if they were true. They were</p> <p>18 publicly available. I didn't have access to the</p> <p>19 data that was used to compile that information,</p> <p>20 so I can't say they were 100% true. I can only</p> <p>21 make a assumption based on the viability of the</p> <p>22 sources that they came from.</p> <p>23 Q. America's drug problem isn't on</p> <p>24 the streets, it's in our medicine cabinets,</p>	<p>1 10:31 to 10:46.</p> <p>2 (Video played as followed:</p> <p>3 "One in four teens reports having</p> <p>4 misused a prescription drug at least</p> <p>5 once. That translates to 5 million</p> <p>6 teenagers, a 33% increase over the past</p> <p>7 five years.")</p> <p>8 MR. BUCHANAN: Let's pause.</p> <p>9 BY MR. BUCHANAN:</p> <p>10 Q. 33% increase in teen abuse of</p> <p>11 prescription drugs between 2009 and 2014.</p> <p>12 You saw that reference, ma'am?</p> <p>13 A. Yes, I did.</p> <p>14 Q. During the same period of time</p> <p>15 that Mr. -- after Mr. Rannazzisi and the DEA had</p> <p>16 sent you a notice saying everybody has got to</p> <p>17 maintain effective controls against diversion,</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. And where we've gotten to by 2014</p> <p>21 is that America's drug problem isn't on the</p> <p>22 street, it's in medicine cabinets, right?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 THE WITNESS: That was the --</p>
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<p>1 right?</p> <p>2 A. It's in a lot of places, but,</p> <p>3 yes, that's one of them.</p> <p>4 Q. What you put in the video is that</p> <p>5 it wasn't on the streets, it was in people's</p> <p>6 medicine cabinets, correct, ma'am?</p> <p>7 MS. VANNI: Object to form.</p> <p>8 THE WITNESS: Because that's what</p> <p>9 the video was focused on.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Is that what you put on the</p> <p>12 video? Not because, not why --</p> <p>13 MS. VANNI: Let her answer her</p> <p>14 question -- her answer.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Not because, not why. Stay with</p> <p>17 my questions.</p> <p>18 What you put in the video, ma'am,</p> <p>19 was that America's drug problem isn't on the</p> <p>20 street, it's in our medicine cabinets, correct?</p> <p>21 MS. VANNI: Object to form.</p> <p>22 THE WITNESS: Yes, the video is</p> <p>23 directed to its audience.</p> <p>24 MR. BUCHANAN: Okay. Let's go to</p>	<p>1 those were the statistics that were in</p> <p>2 the video, yes.</p> <p>3 MR. BUCHANAN: Okay. Well, let's</p> <p>4 go now to towards the end, 11:41.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Okay. And this video was going</p> <p>7 out to pharmacies, right?</p> <p>8 A. That was the focus.</p> <p>9 MR. BUCHANAN: Okay. Could you</p> <p>10 roll it from here, please.</p> <p>11 (Video played as follows:</p> <p>12 "Who is responsible? Yes, it's</p> <p>13 the culture. Yes, it's the doctor or</p> <p>14 prescriber. Yes, it's law enforcement.</p> <p>15 Yes, it's the state boards. But you,</p> <p>16 the pharmacist, have a corresponding</p> <p>17 responsibility. You play a critical</p> <p>18 role.")</p> <p>19 MR. BUCHANAN: Pause, please.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. Did you hear who was listed as</p> <p>22 who's responsible?</p> <p>23 A. Yes.</p> <p>24 Q. Who did the anti-diversion</p>

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<p style="text-align: right;">Page 729</p> <p>1 working group highlight as responsible for this</p> <p>2 situation, ma'am?</p> <p>3 A. Many aspects of the supply</p> <p>4 change.</p> <p>5 Q. I'm sorry. I didn't hear</p> <p>6 manufacturers or distributors mentioned, did</p> <p>7 you?</p> <p>8 MS. VANNI: Object to form.</p> <p>9 THE WITNESS: No, because we had</p> <p>10 DEA controls in place.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. In this video in terms of who is</p> <p>13 responsible for this, the anti-diversion working</p> <p>14 group, Qualitest, other manufacturers, other</p> <p>15 distributors point the finger at culture, right?</p> <p>16 MS. VANNI: Object to form.</p> <p>17 BY MR. BUCHANAN:</p> <p>18 Q. You saw that?</p> <p>19 A. That's what it says, yes.</p> <p>20 Q. Pointed the finger at the DEA,</p> <p>21 right?</p> <p>22 MS. VANNI: Objection.</p> <p>23 THE WITNESS: Yes.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 731</p> <p>1 THE WITNESS: Manufacturers that</p> <p>2 comply with the regulations are not</p> <p>3 contributing to the problem.</p> <p>4 BY MR. BUCHANAN:</p> <p>5 Q. Did you see any reference to</p> <p>6 manufacturers' influence on state boards?</p> <p>7 MS. VANNI: Objection.</p> <p>8 THE WITNESS: No, I would not</p> <p>9 think that that would be applicable to</p> <p>10 this.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. Did you see any reference to</p> <p>13 distributors' influence on state boards?</p> <p>14 A. No.</p> <p>15 Q. Did you see any reference to our</p> <p>16 industry associations that have worked to change</p> <p>17 the treatment of pain so that these drugs could</p> <p>18 be prescribed more broadly, did you see any</p> <p>19 reference to that as a responsibility?</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: No.</p> <p>22 BY MR. BUCHANAN:</p> <p>23 Q. Did you see any reference to</p> <p>24 distributors who had no suspicious order</p>
<p style="text-align: right;">Page 730</p> <p>1 Q. Pointed the finger at doctors,</p> <p>2 right?</p> <p>3 A. Yes, definitely.</p> <p>4 MS. VANNI: Objection.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. And pointed the finger at state</p> <p>7 boards?</p> <p>8 MS. VANNI: Objection.</p> <p>9 THE WITNESS: Yes, definitely.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Okay. And pointed the finger at</p> <p>12 pharmacists, right?</p> <p>13 MS. VANNI: Objection.</p> <p>14 THE WITNESS: Yes, definitely.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. Missed a few big players in the</p> <p>17 supply chain; we agree?</p> <p>18 MS. VANNI: Objection.</p> <p>19 THE WITNESS: I would not agree.</p> <p>20 BY MR. BUCHANAN:</p> <p>21 Q. We could agree that manufacturers</p> <p>22 aren't referenced in terms of their roles in</p> <p>23 influencing state boards, right?</p> <p>24 MS. VANNI: Objection.</p>	<p style="text-align: right;">Page 732</p> <p>1 monitoring programs for years and years and</p> <p>2 years?</p> <p>3 MS. VANNI: Objection.</p> <p>4 THE WITNESS: No.</p> <p>5 BY MR. BUCHANAN:</p> <p>6 Q. Did you see any reference to</p> <p>7 manufacturers who had no such responsibility?</p> <p>8 MS. VANNI: Objection.</p> <p>9 THE WITNESS: No.</p> <p>10 BY MR. BUCHANAN:</p> <p>11 Q. Did you see any reference to the</p> <p>12 30 plus million dollars Endo paid to the NIPC to</p> <p>13 run programs to expand the market for pain?</p> <p>14 MS. VANNI: Objection, beyond the</p> <p>15 scope, argument.</p> <p>16 THE WITNESS: No, and I didn't</p> <p>17 see any reference either to product</p> <p>18 imported illegally or to any other</p> <p>19 scenario, independent thought, any other</p> <p>20 scenario that causes abuse and</p> <p>21 addiction. That was not the focus of</p> <p>22 this video.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. Who is responsible? You endorsed</p>

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<p style="text-align: right;">Page 733</p> <p>1 this?</p> <p>2 A. I did.</p> <p>3 Q. We have your letter, ma'am, from</p> <p>4 October 18, 2013.</p> <p>5 Do you recall that?</p> <p>6 A. I recall the date. I can't</p> <p>7 recall what the letter said, but yes.</p> <p>8 Q. That's where you told all of your</p> <p>9 customers that we all have this responsibility,</p> <p>10 right?</p> <p>11 A. Yes.</p> <p>12 MS. VANNI: Object to form.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. We all have this responsibility,</p> <p>15 manufacturers, correct?</p> <p>16 A. Yes.</p> <p>17 Q. Distributors, correct?</p> <p>18 MS. VANNI: Objection.</p> <p>19 THE WITNESS: Yes.</p> <p>20 MS. VANNI: Objection.</p> <p>21 THE WITNESS: And I consider</p> <p>22 putting that out there to be going above</p> <p>23 and beyond, and that's, again, something</p> <p>24 that I have always wanted to do.</p>	<p style="text-align: right;">Page 735</p> <p>1 Q. Do you recall that question in</p> <p>2 the video?</p> <p>3 A. In this particular video, yes.</p> <p>4 Q. Who is responsible?</p> <p>5 A. Yes.</p> <p>6 Q. Okay. We could agree that the</p> <p>7 Cardinal Healths, the Actavis, the McKessons,</p> <p>8 the Mallinckrodt, the AmerisourceBergens and</p> <p>9 the Qualitest, who sponsored the video, are not</p> <p>10 listed in any way as having responsibility for</p> <p>11 this, correct?</p> <p>12 MS. VANNI: Object to form.</p> <p>13 THE WITNESS: We have a</p> <p>14 responsibility to comply with the</p> <p>15 regulation.</p> <p>16 BY MR. BUCHANAN:</p> <p>17 Q. Do you have my question, ma'am.</p> <p>18 When the question was asked in the video --</p> <p>19 A. They are not listed in the video.</p> <p>20 Q. That's right. But yet you knew,</p> <p>21 you knew when you sent your letter in February</p> <p>22 of 2013 that you had a responsibility as</p> <p>23 Qualitest, correct?</p> <p>24 MS. VANNI: Object to form.</p>
<p style="text-align: right;">Page 734</p> <p>1 MR. BUCHANAN: Could we go to the</p> <p>2 next slide, please, let's finish it.</p> <p>3 (Video played as follows:</p> <p>4 "When you are in that moment of</p> <p>5 truth, will you recognize and act upon</p> <p>6 the red flag?")</p> <p>7 MR. BUCHANAN: Let's pause.</p> <p>8 BY MR. BUCHANAN:</p> <p>9 Q. So we could agree that in terms</p> <p>10 of who has the responsibility, manufacturers and</p> <p>11 distributors and others that had no suspicious</p> <p>12 order monitoring programs or efforts to prevent</p> <p>13 diversion were not listed, correct?</p> <p>14 MS. VANNI: Object to form.</p> <p>15 BY MR. BUCHANAN:</p> <p>16 Q. We can agree on that?</p> <p>17 A. We can agree that everyone has a</p> <p>18 responsibility to abide by the regulations.</p> <p>19 Q. Okay. We can agree that when</p> <p>20 those that had the responsibility for this</p> <p>21 situation, who is responsible was the question.</p> <p>22 Do you recall that?</p> <p>23 MS. VANNI: Object to form.</p> <p>24 BY MR. BUCHANAN:</p>	<p style="text-align: right;">Page 736</p> <p>1 THE WITNESS: Of course. That's</p> <p>2 why we did comply.</p> <p>3 BY MR. BUCHANAN:</p> <p>4 Q. Distributors had that</p> <p>5 responsibility, correct?</p> <p>6 A. Yes.</p> <p>7 Q. And if anyone broke that supply</p> <p>8 -- that closed system, heart-wrenching</p> <p>9 consequences could occur, right?</p> <p>10 A. That's what my letter said, yes.</p> <p>11 Q. Okay. Now, let's focus on a few</p> <p>12 other points you did in examination with</p> <p>13 counsel.</p> <p>14 MR. BUCHANAN: What do we have</p> <p>15 time-wise?</p> <p>16 THE VIDEOGRAPHER: Seven minutes.</p> <p>17 We're at 1:13. Do you want me to go</p> <p>18 off?</p> <p>19 MR. BUCHANAN: No, no, we're</p> <p>20 fine.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Just want to circle back on some</p> <p>23 of the questions about Anda, specifically this</p> <p>24 interaction you had with DEA in the summer of</p>

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<p style="text-align: right;">Page 737</p> <p>1 2007.</p> <p>2 Do you recall that, ma'am?</p> <p>3 A. Yes.</p> <p>4 Q. Okay. I think -- I think defense</p> <p>5 counsel characterized it as an invitation?</p> <p>6 A. Yes.</p> <p>7 Q. You were invited?</p> <p>8 A. Yes.</p> <p>9 Q. Didn't they say they wanted to</p> <p>10 talk to you about serious concerns?</p> <p>11 MS. KOSKI: Object to form.</p> <p>12 THE WITNESS: DEA did, yes.</p> <p>13 BY MR. BUCHANAN:</p> <p>14 Q. They told you they wanted to talk</p> <p>15 to you about serious concerns because certainly</p> <p>16 about certain orders, but also your suspicious</p> <p>17 order monitoring system, correct?</p> <p>18 MS. KOSKI: Object to form.</p> <p>19 THE WITNESS: Anda's suspicious</p> <p>20 order monitoring system.</p> <p>21 BY MR. BUCHANAN:</p> <p>22 Q. Yeah, the year was a little</p> <p>23 confusing there, but Anda's suspicious order</p> <p>24 monitoring system, correct?</p>	<p style="text-align: right;">Page 739</p> <p>1 Did I read that correctly?</p> <p>2 A. He did indicate that.</p> <p>3 Q. About Anda, that he would like to</p> <p>4 discuss, okay.</p> <p>5 You understood he had concerns?</p> <p>6 A. That's yes.</p> <p>7 Q. Okay. You started to read I</p> <p>8 think the first sentence in the bottom of page 1</p> <p>9 of Exhibit 32, Bates stamp 959. "Mr. Mapes then</p> <p>10 went on to say that since then, they have seen a</p> <p>11 steady increase in Anda's sales of hydrocodone,</p> <p>12 to the point of these sales being extremely</p> <p>13 questionable."</p> <p>14 Do you recall that?</p> <p>15 A. These were the -- yes, it's a</p> <p>16 summary of what he was saying during the call.</p> <p>17 Q. And he said that many of the</p> <p>18 retail pharmacies that you were selling to were</p> <p>19 feeding the drugs to illegal internet</p> <p>20 pharmacies, right?</p> <p>21 MS. KOSKI: Object to form.</p> <p>22 THE WITNESS: That's what he</p> <p>23 said, yes.</p> <p>24 BY MR. BUCHANAN:</p>
<p style="text-align: right;">Page 738</p> <p>1 A. Yes.</p> <p>2 Q. And you parsed the language</p> <p>3 closely in some areas with counsel. I'd like</p> <p>4 you now to look at Exhibit 32 that was marked in</p> <p>5 examination. I don't have the ability to pull</p> <p>6 it up on the screen for you, ma'am. It's the</p> <p>7 e-mail exchange on July 16th, 2007 between</p> <p>8 yourself and Diane -- Ms. Miranda?</p> <p>9 A. Yes.</p> <p>10 Q. Okay. This is an interaction</p> <p>11 phone call you had with a Mr. Mapes from the</p> <p>12 DEA.</p> <p>13 A. Hold on. I just have one page.</p> <p>14 Q. This is an interaction you had</p> <p>15 with a Mr. Mapes from the DEA, correct?</p> <p>16 A. It is a documented detail of that</p> <p>17 descript -- that phone call, yes.</p> <p>18 Q. You got a phone call, right?</p> <p>19 A. Yes.</p> <p>20 Q. First call was, hey, does Watson</p> <p>21 own Anda now, right?</p> <p>22 A. Correct.</p> <p>23 Q. Okay. He then indicated he had</p> <p>24 concerns.</p>	<p style="text-align: right;">Page 740</p> <p>1 Q. He then said he had questions</p> <p>2 about the effectiveness of Anda's suspicious</p> <p>3 order monitoring system, correct?</p> <p>4 A. He asked about the effectiveness,</p> <p>5 which I couldn't really comment on, having not</p> <p>6 worked there.</p> <p>7 Q. Yeah, and that was interesting.</p> <p>8 I think you were asked a question by defense</p> <p>9 counsel about did Anda have its own DEA</p> <p>10 compliance group.</p> <p>11 Do you recall that?</p> <p>12 A. Yes.</p> <p>13 Q. When the time came after you</p> <p>14 were -- I think you said summoned in your</p> <p>15 characterization of this?</p> <p>16 A. I did.</p> <p>17 Q. After you were summoned to go and</p> <p>18 meet with the DEA in Washington, who came with</p> <p>19 you from DEA compliance at Anda?</p> <p>20 A. I believe Michael Cochrane.</p> <p>21 Q. CEO?</p> <p>22 A. I'm not sure what his title was,</p> <p>23 but he was the person who at the time I was told</p> <p>24 handled DEA compliance.</p>

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<p style="text-align: right;">Page 741</p> <p>1 Q. Okay. Well, let's look at your</p> <p>2 writing in Exhibit 2. Exhibit 2 is your summary</p> <p>3 of your experience at Ciba-Geigy, Watson,</p> <p>4 Qualitest, et cetera; do you recall?</p> <p>5 A. Yes.</p> <p>6 Q. And you note in the middle of the</p> <p>7 description --</p> <p>8 MR. BUCHANAN: Could we pull up</p> <p>9 1146.2 and go to the Watson entry in the</p> <p>10 middle of the paragraph.</p> <p>11 BY MR. BUCHANAN:</p> <p>12 Q. It says, "However, Watson</p> <p>13 purchased Anda and certainly afterward, Anda was</p> <p>14 summoned to DEA as a result of their lack of a</p> <p>15 robust SOM program."</p> <p>16 Did I read that correctly?</p> <p>17 A. You did.</p> <p>18 Q. "I did not support Anda from a</p> <p>19 DEA perspective as they had come to Watson with</p> <p>20 their own DEA person."</p> <p>21 And it notes, however, you were</p> <p>22 asked to be their DEA representative for the</p> <p>23 meeting in HQ.</p> <p>24 Did I read that correctly?</p>	<p style="text-align: right;">Page 743</p> <p>1 A. For cause.</p> <p>2 Q. For cause. It wasn't just a</p> <p>3 regular distributor meeting that you talked</p> <p>4 about having -- being aware of that was</p> <p>5 happening in the industry, correct?</p> <p>6 A. Actually, it was a bad choice of</p> <p>7 words.</p> <p>8 Q. You've told us about several</p> <p>9 words that I think you'd rather recast in your</p> <p>10 oral testimony, but what you wrote when you were</p> <p>11 characterizing your experience, on reflection at</p> <p>12 Watson, was that the DEA meeting was for cause,</p> <p>13 correct?</p> <p>14 A. That's what I wrote, yes.</p> <p>15 Q. And that "immediate action was</p> <p>16 required," that's what you wrote, right?</p> <p>17 A. Yes.</p> <p>18 Q. "Immediate action required,"</p> <p>19 correct?</p> <p>20 A. That's what I wrote, yes.</p> <p>21 Q. Not suggested, right?</p> <p>22 A. That's what I wrote, yes.</p> <p>23 Q. Not just to go above and beyond,</p> <p>24 right?</p>
<p style="text-align: right;">Page 742</p> <p>1 A. Yes.</p> <p>2 Q. And what you listed for the</p> <p>3 people that you went with to that meeting were a</p> <p>4 representative of the legal department, correct?</p> <p>5 You can read it in the next</p> <p>6 sentence.</p> <p>7 A. Yes.</p> <p>8 Q. What you listed --</p> <p>9 A. I don't know who the legal person</p> <p>10 was.</p> <p>11 Q. You went with legal and the</p> <p>12 individual who at the time was the president of</p> <p>13 Anda, correct?</p> <p>14 A. Yes.</p> <p>15 Q. And we talked about the binder</p> <p>16 you got, and I won't revisit that.</p> <p>17 But then you note, however --</p> <p>18 well, actually, we probably should. "DEA</p> <p>19 presented and provided a binder as they have</p> <p>20 done for most companies at this point" in time.</p> <p>21 Do you see that?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. "However, in Anda's case</p> <p>24 the DEA meeting was" what?</p>	<p style="text-align: right;">Page 744</p> <p>1 A. Yes.</p> <p>2 Q. Required?</p> <p>3 A. As written.</p> <p>4 Q. That's what you wrote?</p> <p>5 A. As written, yes.</p> <p>6 Q. Okay. Anda then revamped their</p> <p>7 program and we conveyed the results to the DEA.</p> <p>8 Did I read that correctly?</p> <p>9 A. You did.</p> <p>10 Q. Okay. Mr. Mapes, you referenced</p> <p>11 an interaction with him in this 2007 period of</p> <p>12 time.</p> <p>13 Is that the same Mr. Mapes that</p> <p>14 Qualitest brought in to evaluate their program</p> <p>15 in 2008 that we looked at yesterday?</p> <p>16 A. Yes, I believe so.</p> <p>17 Q. That identified inadequacies with</p> <p>18 the SOM program at Qualitest?</p> <p>19 MS. VANNI: Object to form, and I</p> <p>20 think we're at time.</p> <p>21 THE WITNESS: Again, I'm not</p> <p>22 sure.</p> <p>23 BY MR. BUCHANAN:</p> <p>24 Q. What's that?</p>

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<p style="text-align: right;">Page 745</p> <p>1 A. Again, I'm not sure.</p> <p>2 MR. BUCHANAN: Okay. If that's</p> <p>3 the case, is that accurate? Okay. Let</p> <p>4 me -- for to correct one thing on the</p> <p>5 record, counsel, I'm just going to mark</p> <p>6 this and you can have it.</p> <p>7 (Document marked for</p> <p>8 identification as Par-Norton Deposition</p> <p>9 Exhibit No. 41.)</p> <p>10 MR. BUCHANAN: This is Exhibit</p> <p>11 41. It's the -- I'm passing it over to</p> <p>12 the witness.</p> <p>13 I'll represent to counsel that</p> <p>14 Exhibit 41 is the remainder of the</p> <p>15 spreadsheet data that Endo/Qualitest has</p> <p>16 pointed plaintiffs' counsel to as</p> <p>17 representative of -- as containing the</p> <p>18 sales and shipping data of the company's</p> <p>19 various controlled substances. That</p> <p>20 Bates number should correlate with the</p> <p>21 summary exhibit, which is Exhibit 4, as</p> <p>22 a data source.</p> <p>23 Thank you, ma'am. I'm told I'm</p> <p>24 out of time.</p>	<p style="text-align: right;">Page 747</p> <p>1 C E R T I F I C A T I O N</p> <p>2 I, MARGARET M. REIHL, a</p> <p>3 Registered Professional Reporter,</p> <p>4 Certified Realtime Reporter, Certified</p> <p>5 Shorthand Reporter, Certified LiveNote</p> <p>6 Reporter and Notary Public, do hereby</p> <p>7 certify that the foregoing is a true and</p> <p>8 accurate transcript of the testimony as</p> <p>9 taken stenographically by and before me</p> <p>10 at the time, place, and on the date</p> <p>11 hereinbefore set forth.</p> <p>12 I DO FURTHER CERTIFY that I</p> <p>13 am neither a relative nor employee nor</p> <p>14 attorney nor counsel of any of the</p> <p>15 parties to this action, and that I am</p> <p>16 neither a relative nor employee of such</p> <p>17 attorney or counsel, and that I am not</p> <p>18 financially interested in the action.</p> <p>19</p> <p>20</p> <p>21 -----</p> <p>22 Margaret M. Reihl, RPR, CRR, CLR</p> <p>23 CSR #XI01497 Notary Public</p> <p>24</p>
<p style="text-align: right;">Page 746</p> <p>1 THE WITNESS: Thank you.</p> <p>2 MR. BUCHANAN: I appreciate your</p> <p>3 indulgence. Off the record.</p> <p>4 THE VIDEOGRAPHER: The time is</p> <p>5 11:56. Off the record.</p> <p>6 (Brief recess.)</p> <p>7 THE VIDEOGRAPHER: 12:06, back on</p> <p>8 the record.</p> <p>9 MR. BUCHANAN: Ms. Norton, I'm</p> <p>10 advised that I'm out of time. I have no</p> <p>11 further questions at this time.</p> <p>12 Counsel, your witness.</p> <p>13 MS. VANNI: I have no questions</p> <p>14 at this time. Thank you.</p> <p>15 THE VIDEOGRAPHER: The time is</p> <p>16 now 12:06 p.m. This concludes today's</p> <p>17 portion of the deposition of Tracey</p> <p>18 Norton. We are now off the record.</p> <p>19 (Witness excused.)</p> <p>20 ---</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 748</p> <p>1 - - - - -</p> <p>2 E R R A T A</p> <p>3 - - - - -</p> <p>4 PAGE LINE CHANGE</p> <p>5 _____</p> <p>6 REASON: _____</p> <p>7 _____</p> <p>8 REASON: _____</p> <p>9 _____</p> <p>10 REASON: _____</p> <p>11 _____</p> <p>12 REASON: _____</p> <p>13 _____</p> <p>14 REASON: _____</p> <p>15 _____</p> <p>16 REASON: _____</p> <p>17 _____</p> <p>18 REASON: _____</p> <p>19 _____</p> <p>20 REASON: _____</p> <p>21 _____</p> <p>22 REASON: _____</p> <p>23 _____</p> <p>24 REASON: _____</p>

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ACKNOWLEDGMENT OF DEPONENT

I, TRACEY L. NORTON, do hereby
certify that I have read the foregoing
pages, and that the same is a correct
transcription of the answers given by me
to the questions therein propounded,
except for the corrections or changes in
form or substance, if any, noted in the
attached Errata Sheet.

TRACEY L. NORTON DATE

Subscribed and sworn to before me this

_____ day of _____, 2018.

My commission expires: _____

Notary Public